

EXHIBIT A

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION)	
OPIATE LITIGATION)	MDL No. 2804
)	
THIS DOCUMENT RELATES TO:)	Case No. 1:17-md-2804
)	
<i>The Blackfeet Tribe of the Blackfeet Indian</i>)	Judge Dan Aaron Polster
<i>Reservation v. AmerisourceBergen Drug</i>)	
<i>Corporation, et al.</i>)	
Case No. 1:18-op-45749)	
)	

**DEFENDANT ALBERTSON’S LLC’S JOINDER OF MOTION TO DISMISS FIRST
AMENDED COMPLAINT BY DEFENDANTS CVS PHARMACY, INC., CVS INDIANA,
L.L.C., WALMART INC., WALGREEN CO., AND WALGREEN ARIZONA DRUG CO.**

Defendant Albertson’s LLC hereby joins in Defendants CVS Pharmacy, Inc., CVS Indiana, L.L.C., Walmart Inc., Walgreen Co., and Walgreen Arizona Drug Co.’s Motion to Dismiss the First Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) (ECF No. 927, 1:17-md-02804), Memorandum in Support of the Motion to Dismiss (ECF. No. 927-1), and Reply in Support of the Motion to Dismiss (ECF. No. 1085),¹ and states as follows:

INTRODUCTION

On August 3, 2018 the Blackfeet Tribe (“Plaintiff”) named Albertson’s LLC (“Albertson’s”) as a “Distributor Defendant” in its First Amended Complaint. (See ECF No. 1128, 1:17-md-02804, at ¶ 90). Over five months later and after briefing had already been completed on the motion to dismiss brought by CVS Pharmacy, Inc., CVS Indiana, L.L.C., Walmart Inc., Walgreen Co., and Walgreen Arizona Drug Co. (“the Moving Defendants”), Albertson’s was first

¹ The ECF references correspond to the Master Docket, Case No. 1:17-md-02804. Identical briefing has been filed in the individual case docket, Case No. 1:18-op-45749. See ECF No. 21 (Def. Motion to Dismiss); ECF No. 21-1 (Def. Memo. in Support); ECF No. 36 (Def. Reply).

served with Plaintiff's First Amended Complaint (*See* ECF No. 40, 1:18-op-45749). As such, Albertson's was deprived of any opportunity to help shape the Moving Defendant's motion to dismiss and now joins, adopts, and incorporates by reference the legal arguments and authorities cited in the Moving Defendants' motion to dismiss briefings. Beyond the arguments expressed by the Moving Defendants, Albertson's underscores that Plaintiff's First Amended Complaint is devoid of any substantive factual allegations that would support any claims against Albertson's, either as a dispensing pharmacy or as a retailer with an internal distribution function. Additionally, Albertson's calls the Court's attention to a recent decision from the Delaware Superior Court which supports the Moving Defendants' arguments that Plaintiff's claims are improperly based on speculative, conclusory allegations and must be dismissed.

ARGUMENT

I. Albertson's LLC Joins the Moving Defendants' Motion to Dismiss.

Albertson's respectfully joins the Moving Defendants' motion to dismiss briefings and adopts the arguments raised therein, pursuant to section 2(g) of Case Management Order One. (*See* ECF 232, 1:17-md-02804) (directing parties to "coordinate and consolidate briefing on all of the motions to dismiss"). In doing so, Albertson's reserves all rights to raise any defenses not addressed in the Moving Defendants' motion to dismiss and to file its own individual motion to dismiss. (*See id.* at §§ 2(j) and 2(k)).

In their motion to dismiss, the Moving Defendants argue that Plaintiff's First Amended Complaint should be dismissed because Plaintiff lacks Article III standing and because Plaintiff's claims are barred by the Free Public Services Doctrine. (*See* Moving Def. Memo., Parts I and VIII). The Moving Defendants also argue that Plaintiff fails to state claims of public nuisance, negligence, unjust enrichment, civil conspiracy, and violations of Montana's Unfair Trade

Practices and Consumer Protection Act. (*See* Moving Def. Memo., Parts III, IV, V, VI, and VII). Finally, the Moving Defendants argue that to the extent that Plaintiff attempts to bring claims against them as retail pharmacies, such claims are inadequately pled and must be dismissed. (*See* Moving Def. Memo., Part II). All these arguments apply with equal force to the claims brought against Albertson's.²

Further, to echo a point made throughout the Moving Defendant's motion, Plaintiff largely fails to allege any *specific* acts committed by the Moving Defendants in support of its claims but rather relies on "cursory assertions" and "boilerplate legal conclusions." (*See, e.g.*, Moving Def. Memo., at 6, 11). This, of course, falls short of the *Iqbal/Twombly* "plausibility" requirement and falls well short of Fed. R. Civ. P. 9(b)'s heightened pleading requirement, which applies to some of Plaintiff's claims. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."); *see also Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 253 (6th Cir. 2012) (discussing Rule 9(b) standard as applied to negligent misrepresentation claim and granting dismissal). As such, the Court should disregard any conclusory or unsupported allegations in ruling on the Moving Defendant's motion to dismiss. *See Terry v. Tyson Farms*,

² Although Plaintiff describes Albertson's as a "wholesale distributor in Montana", Plaintiff acknowledges that the number of doses of prescription opioids purportedly distributed by Albertson's is significantly smaller than those distributed by major distributors such as Cardinal Health, Inc. and McKesson Corporation. (*See* ECF No. 1128, 1:17-md-02804, at ¶¶ 90, 698). Given Plaintiff's pleading failure, the arguments made in the Major Distributors' Motion to Dismiss briefings also apply to the claims brought against Albertson's and the Moving Defendants, except for those addressing Plaintiff's RICO claims, which are not brought against Albertson's. (*See generally* ECF No. 924, 1:17-md-02804) (Dist. Memo. in Support). As such, Albertson's reiterates that the arguments made in the Major Distributors' Motion to Dismiss are fully incorporated into the Moving Defendants' briefings. (*See* Moving Def. Memo., at 1) ("The Moving Defendants incorporate the arguments submitted in the Major Distributors' brief in support of their motion to dismiss the Complaint...").

Inc., 604 F.3d 272, 276 (6th Cir. 2010) (“We need not accept as true legal conclusions or unwarranted factual inferences, and conclusory allegations or legal conclusions masquerading as factual allegations will not suffice.”) (citations and quotations omitted).

Moreover, many allegations in the First Amended Complaint should also be disregarded because they are based on nothing more than “information and belief.” For instance, Plaintiff alleges “upon information and belief” that the Moving Defendants failed to adequately train pharmacists on how to handle opioid prescriptions, failed to adequately use available data to identify suspicious opioid prescriptions, failed to otherwise scrutinize opioid prescriptions they received, and failed to respond to certain concerns raised by their employees. (*See* ECF No. 1128, 1:17-md-02804, at ¶¶ 600-605). But these allegations amount to mere speculation. Couching them in terms of “information and belief” does nothing to help Plaintiff because the “mere fact that someone believes something to be true does not create a plausible inference that it is true.” *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 931 (6th Cir. 2014) (affirming dismissal of “failure-to-update” claim and noting “upon information and belief” allegations impermissible); *see also 16630 Southfield Ltd. P’ship v. Flagstar Bank, F.S.B.*, 727 F.3d 502, 505-06 (6th Cir. 2013) (dismissing discrimination-based claim which was based on series of “upon information and belief” allegations because plaintiffs “merely alleged their ‘belief’”). As such, the Court should disregard any allegations based on nothing more than “information and belief” in ruling on the Moving Defendant’s motion to dismiss.

II. Plaintiff’s First Amended Complaint Is Completely Devoid of Any Substantive Factual Allegations Against Albertson’s That Would Support its Claims.

In moving to join the motion to dismiss, Albertson’s also emphasizes that Plaintiff’s allegations against Albertson’s are devoid of any specific facts. Plaintiff alleges no facts to justify its claims that Albertson’s is a “Distributor Defendant,” nor does it allege any fact or wrongdoing

by Albertson's beyond conclusory or speculative allegations against "Distributor Defendants" as a whole. Further, while the First Amended Complaint does contain *some* factual allegations against certain Distributor Defendants, none of these allegations are directed at Albertson's and thus do not support Plaintiff's claims against Albertson's. As such, Plaintiff's vague allegations prevent Albertson's from comprehending Plaintiff's claims and meaningfully responding to those claims.

Indeed, Albertson's is mentioned in *just four* (4) of the 1124 paragraphs contained in the First Amended Complaint. (*See* ECF No. 1128, 1:17-md-02804, at ¶¶ 1, 90, 96, 698). Three of those mentions are introductory paragraphs that merely define or describe Albertson's. (*See id.* at ¶¶ 1, 90, 96). The fourth paragraph purportedly states how many opioid shipments Albertson's made to Plaintiff's geographic region over a nine-year period and, notably, reflects that Albertson's did not distribute *any* shipments in six of those nine years. (*See id.* at ¶ 698). That is all.

As best Albertson's can tell from the face of the complaint, Plaintiff then attempts to lump it in whenever Plaintiff refers generally to "Defendants" or "Distributor Defendants." This is inadequate and warrants dismissal. *See e.g., Eberhard Architects, LLC v. Bogart Architecture, Inc.*, No. 1:14 CV 1185, 2014 WL 4354561, at *3 (N.D. Ohio Aug. 29, 2014) (dismissing copyright infringement claim against defendant lender where complaint only had specific allegation that defendant was the lender and then the "remaining allegations lump[ed] all defendants together"). Finding otherwise would leave Albertson's "to speculate in responding to allegations in the Amended Complaint, which may prejudice its defense." *Eberhard v. Chicago Title Ins. Co.*, No. 1:11 CV 834, 2012 WL 13029534, at *13 (N.D. Ohio Mar. 31, 2012) (finding fraud claim insufficient where complaint "merely lump[ed] allegations against all Defendants together,

regardless of their role”); *see also Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992) (dismissing fraud claim for same reason).³

Relatedly, many of the allegations Plaintiff makes against certain Distributor Defendants cannot be used to support its claims against Albertson’s. For instance, Plaintiff incorporates details of fines and settlement agreements involving certain Distributor Defendants in order to allege that Defendants generally failed to prevent diversion of opioids. (*See* ECF No. 1128, 1:17-md-02804, at ¶¶ 564-585). But facts relating to enforcement actions brought against other Distributor Defendants in places other than Montana do not support Plaintiff’s claims against Albertson’s. Plaintiff also cites certain enforcement actions brought against certain retail Defendants, but not Albertson’s, to allege that Defendants dubbed as the “National Retail Pharmacies” failed to comply with state and federal law governing distributing and dispensing prescription opioids. (*See* ECF No. 1128, 1:17-md-02804, at ¶¶ 606-635). But again, allegations directed at other Distributor Defendants do not support Plaintiff’s claims against Albertson’s. Indeed, none of Plaintiff’s allegations aimed at the “National Retail Pharmacies” would even apply to Albertson’s because, by Plaintiff’s own definition, Albertson’s is not being sued as a “National Retail Pharmacy” Defendant. *See* ECF No. 1128, 1:17-md-02804, at ¶ 95) (defining the “National Retail Pharmacies” as only including CVS, Walgreens, and Walmart).

Simply put, when the vague, collective allegations and irrelevant allegations relating to other Distributor Defendants are disregarded—as they should be—Plaintiff utterly fails to plead

³ For instance, Plaintiff speaks generally about “Defendants” and “Distributor Defendants” when alleging that they worked in concert to inflate opioid quotas through organizations like the Pain Care Forum or the Healthcare Distribution Alliance (“HDA”) but provides no allegations about Albertson’s role specifically. (*See* ECF No. 1128, ¶¶ 513-538). Indeed, it claims that “each of the Distributor Defendants” were members of the HDA and incorporates the HDA’s website for reference, but Albertson’s is not identified as a member on the website. (*See* <https://www.hda.org/about/membership/distributor>).

“sufficient factual matter” against Albertson’s “to state a claim to relief that is plausible on its face.” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570) (quotations omitted).

Additionally, this Court has made clear its intention that plaintiffs amend their complaints “to remove claims against defendants who should *not* be named,” and the Court has taken steps to facilitate this by, for instance, ordering the production of ARCOS data. (*See* ECF 739, 1:17-md-02804, at 1) (quotations omitted); (*see also* ECF 397, 1:17-md-02804) (ordering the production of ARCOS data for entire United States to better help MDL proceed based on facts and “not conjecture or speculation”). In light of these orders, Albertson’s also files its joinder at this time to give Plaintiff the opportunity to review the facts and make the appropriate decision on its own to dismiss Albertson’s.

III. The Delaware Superior Court’s Recent Decision in *State of Delaware, ex rel. Kathleen Jennings v. Purdue Pharma L.P.* Further Supports Dismissal.

As a final note, Albertson’s calls to the Court’s attention a recent decision that was issued after the Moving Defendants’ motion was fully briefed. *State of Delaware, ex rel. Kathleen Jennings v. Purdue Pharma L.P., et al.*, No. CVN18C01223MMJCCD, 2019 WL 446382, at *1 (Del. Super. Ct. Feb. 4, 2019) (attached as Exhibit 1). The Delaware court’s decision, although not precedential, provides further support for the Moving Defendant’s arguments to dismiss Plaintiff’s negligence claims and civil conspiracy claim. Like Plaintiff here, the State of Delaware brought various claims against opioid manufacturers, distributors, and pharmacies. *Id.* at *1-2. In relevant part, the state argued that pharmacies have a duty to prevent opioid diversion and to report any suspicious activity and that they breached that duty by failing to identify “red flags” and failing to

report suspicious orders. *Id.* at 9. The court found that the state’s allegations were “entirely speculative and conclusory” and dismissed the claims against the defendant pharmacies.⁴ *Id.* at 11.

The court’s ruling on the state’s civil conspiracy claim is also instructive. The state alleged a civil conspiracy among all defendants—manufacturers, distributors, and pharmacies—but the court found the state had only alleged parallel conduct, which was insufficient to state a claim. *Id.* at 14. Like the Plaintiff here, the state had failed to allege that the “participants had knowingly and willfully conspired in the scheme.” *Id.* (quotations and citations omitted). The court was unpersuaded by the state’s allegation that the “[d]efendants had attended the same conferences” and ruled that the state had failed to adequately allege the elements of conspiracy. *Id.* So too here.

CONCLUSION

For the foregoing reasons and for the reasons stated by the Moving Defendants whose Motion to Dismiss Albertson’s LLC joins and incorporates herein, Albertson’s LLC respectfully requests that Plaintiff’s First Amended Complaint be dismissed.

Dated: February 15, 2019

Respectfully Submitted,

By: /s/ Francis A. Citera
One of Defendant’s Attorneys

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⁴ The court dismissed the claims without prejudice to the extent that the state was attempting to bring claims sounding in medical negligence to allow the state to comply with Delaware law by amending their claims and including an “affidavit of merit.” *See id.* at 11.

EXHIBIT 1

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

STATE OF DELAWARE, <i>ex rel.</i>)	
KATHLEEN JENNINGS, Attorney)	
General of the State of Delaware,)	
)	
Plaintiff,)	C.A. No. N18C-01-223 MMJ CCLD
)	
v.)	
)	
PURDUE PHARMA L.P.; PURDUE)	
PHARMA INC.; THE PURDUE)	
FREDERICK COMPANY; ENDO)	
HEALTH SOLUTIONS INC.;)	
ENDO PHARMACEUTICALS INC.;)	
MCKESSON CORPORATION;)	
CARDINAL HEALTH INC.;)	
AMERISOURCEBERGEN)	
CORPORATION; ANDA)	
PHARMACEUTICALS, INC.; H.D.)	
SMITH, LLC; CVS HEALTH)	
CORPORATION; and WALGREENS)	
BOOTS ALLIANCE, INC.,)	
)	
Defendants.)	

Submitted: November 15, 2018

Decided: February 4, 2019

Upon Defendants' Motions to Dismiss and Motion to Strike

Ryan P. Newell, Esq., Shaun Michael Kelly, Esq., Kyle Evans Gay, Esq., Connolly Gallagher, LLP, Wilmington, Delaware; Richard W. Fields, Esq., Fields PLLC, Washington, District of Columbia; Scott W. Gilbert, Esq., Richard Shore, Esq. (Argued), Mark A. Packman, Esq., Jenna A. Hudson, Esq. (Argued), Michael B. Rush, Esq. (Argued), Monique T. Abrishami, Esq., Richard J. Leveridge, Esq., Gilbert LLP, Washington, District of Columbia; Kathleen Jennings, Attorney General, Michael Vild, Esq., Michelle Whalen, Esq., Delaware Department of Justice, *Attorneys for the State of Delaware.*

Brian D. Tome, Esq., Kelly E. Rowe, Esq., Reilly, McDevitt, & Henrich, PC, Wilmington, Delaware; Mark S. Cheffo, Esq., Hayden A. Coleman, Esq. (Argued), Debra D. O’Gorman, Esq., Dechert LLP, New York, New York; Judy L. Leone, Esq., Dechert LLP, Philadelphia, Pennsylvania, *Attorneys for Defendant Purdue Pharma L.P. & The Purdue Frederick Company (“Purdue Pharma”)*.

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JOHNSTON, J.

PROCEDURAL CONTEXT

The State of Delaware (“State”), ex rel. Kathleen Jennings,¹ Attorney General of the State of Delaware, brought this suit seeking compensatory, punitive, and other damages, as well as restitution, disgorgement, and civil penalties.

Defendants are: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Endo Health Solutions Inc., and Endo Pharmaceuticals Inc.

(collectively, “Manufacturers”); McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda Pharmaceuticals, Inc., and H. D. Smith, LLC (collectively, “Distributors”); and CVS Health Corporation and Walgreens Boots Alliance, Inc. (collectively, “Pharmacies”).

As to the Manufacturers, the State argues that Manufacturers have duties to

¹ At the time the pending motions were heard, Matthew P. Denn was Attorney General.

disclose accurately the risks associated with opioid medications, specifically, the high risk of addiction and subsequent misuse. The State contends that Manufacturers misrepresented those risks through multi-million-dollar advertising campaigns, and inaccurately claimed that those who were showing signs of addiction were not actually addicted. The State argues that these misstatements were targeted for maximum effect and to a specific audience. The State contends that Manufacturers knew or should have known that their statements were false and misleading. Because they knew the statements were misleading, Manufacturers violated their duties to disclose accurately the risks of using purportedly highly dangerous opioid medications.

As to Distributors, the State argues that Distributors have duties to actively prevent opioid diversion.² The State asserts that both Delaware and federal law have established the duties of care that Distributors must follow. The State argues that, as evidenced by prior regulatory actions against Distributors for failing to prevent diversion, Distributors have violated their duties.

Similarly, as to Pharmacies, the State argues that Pharmacies have duties to prevent opioid diversion and to report any suspicious orders. The State alleges that Pharmacies repeatedly have failed to report suspicious orders made obvious to

² Drug diversion refers to the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

them by certain “red flags,” such as unusually large orders, repetitive orders, and improperly filled orders. The State argues that Pharmacies have violated their duties owed to the State, as evidenced by prior regulatory actions against Pharmacies.

The State argues that Defendants’ collective misconduct has harmed and continues to harm the State of Delaware and its citizens.³ The State alleges the following:

Count I: Consumer Fraud (Against Manufacturer Defendants)

Count II: Nuisance (Against Manufacturer Defendants)

Count III: Negligence (Against Manufacturer Defendants)

Count IV: Unjust Enrichment (Against Manufacturer Defendants)

Count V: Consumer Fraud (Against Distributor Defendants and Pharmacy Defendants)

Count VI: Nuisance (Against Distributor Defendants and Pharmacy Defendants)

Count VII: Negligence (Against Distributor Defendants and Pharmacy Defendants)

³ In recent years, the frequency of opioid use for both chronic pain and non-medical purposes has grown dramatically, resulting in an epidemic of prescription opioid abuse. According to the Centers for Disease Control and Prevention (“CDC”), Delaware lost 669 people to drug overdose deaths between 2014 and 2016. The alleged “main driver” of such deaths was prescription and illicit opioids.

Count VIII: Unjust Enrichment (Against Distributor Defendants and Pharmacy Defendants)

Count IX: Civil Conspiracy (Against Manufacturer Defendants, Distributor Defendants, Pharmacy Defendants).

Defendants have filed Motions to Dismiss. Manufacturers joined together to file one Motion to Dismiss. Four of the five Distributors filed Motions to Dismiss: McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation have jointly filed one motion. Anda Pharmaceuticals, Inc. has separately filed its own motion. The remaining distributor, H.D. Smith, LLC, has not joined in or filed its own motion to dismiss, but did answer the complaint. The Pharmacies jointly filed one motion to dismiss. Oral Argument was heard over two days: October 24, 2018 and November 15, 2018.

MOTION TO DISMISS STANDARD

In a Rule 12(b)(6) Motion to Dismiss, the Court must determine whether the claimant “may recover under any reasonably conceivable set of circumstances susceptible of proof.”⁴ The Court must accept as true all well-pleaded allegations.⁵

⁴ *Spence v. Funk*, 396 A.2d 967, 968 (Del.1978).

⁵ *Id.*

Every reasonable factual inference will be drawn in the non-moving party's favor.⁶ If the claimant may recover under that standard of review, the Court must deny the Motion to Dismiss.⁷

ANALYSIS

NEGLIGENCE AND CONSUMER FRAUD

The State contends that all Defendants violated statutory and common law duties, which caused injury to the State. The State's claims vary slightly as to each class of Defendant.

Manufacturers

State's Allegations

The State argues that each Manufacturer Defendant has a legal obligation under Delaware statutory and common law to exercise reasonable care in the marketing, promotion, and sale of opioids. The State argues that Manufacturers' duties are established by 16 *Del. C.* § 3302, which states: "No person shall manufacturer, sell or trade in, within this State, any article of food or drugs which

⁶ *Wilmington Sav. Fund. Soc 'v, F.S.B. v. Anderson*, 2009 WL 597268, at *2 (Del. Super.) (citing *Doe v. Cahill*, 884 A.2d 451, 458 (Del.2005)).

⁷ *Spence*, 396 A.2d at 968.

is . . . misbranded . . . within the meaning of this chapter.”⁸

The State argues that Manufacturers have breached their duties by misstating facts and by failing to disclose accurately the risks associated with the use of opioids. The State claims that Manufacturers have done this via a multi-million-dollar advertising campaign that is run through websites, promotional materials, live conferences, publications for doctors, and other vehicles. The State asserts that Manufacturers trained pharmaceutical salesmen to tell doctors that the risk of opioid addiction is less than 1%, which is contrary to Center for Disease Control (“CDC”) findings that suggest that there are significant risks of serious opioid addiction and abuse. The CDC reports that about 26% of long term users experience problems with addiction or dependence.⁹ The State claims although there are warning labels approved by the Food and Drug Administration (“FDA”) on the bottles of medication, the content in the advertising campaign is inconsistent with those warning labels in that the advertising scheme significantly minimizes

⁸ See 16 Del. C. § 3308 (“For the purposes of this chapter, a drug is deemed to be misbranded: (1) If it is an imitation of or offered for sale under the name of another drug; (2) If the contents of the package as originally put up were removed, in whole or in part, and other contents were placed in such package or if the package fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate or acetanilide, or any derivative or preparation of any such substances contained therein; (3) If its package or label bears any statement, design or device regarding such article, or the ingredients or substances contained therein which is false or misleading in any particular way; (4) If it is included in the definition of misbranding in the Federal Food, Drug and Cosmetic Act.”).

⁹ Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

the risks.

Further, the State argues that Manufacturers stated that patients who showed signs of addiction were not actually addicted to opioids. The State claims that Manufacturers published a physician education pamphlet which suggested that patients who showed signs of addiction were actually in need of more medication, a phenomenon Manufacturers refer to as “pseudoaddiction.” The State argues that “pseudoaddiction,” a term coined by a Manufacturer, is a concept rejected by the CDC because it lacks scientific evidence. The State claims that Manufacturers advocate for increasing dosages regardless of a patient’s actual prescribed dosage. The State contends that, through their web content, Manufacturers actually encourage patients, who believe they have not been prescribed an adequate dose, to seek a different doctor who will prescribe them the dose they feel they require. The State asserts that Manufacturers claim there is no risk of addiction when the dosage is increased.

The State argues that Manufacturers’ conduct amounts to a breach of duty owed to the State.

Manufacturers’ Response

Manufacturers argue first that the State’s claims are preempted because the FDA has approved opioid medications for the treatment of pain. Manufacturers

maintain that they have complied with the FDA's warning label requirements.

Manufacturers argue that the State cannot impose a duty to alter FDA-approved medicine. Further, Manufacturers assert that courts repeatedly have held that state law claims are preempted where they would require a manufacturer to make statements about safety or efficacy that are inconsistent with what the FDA has required.

Manufacturers also argue that the State has failed to allege causation. Manufacturers argue that the State has failed to identify any physician who heard the alleged misrepresentations and subsequently prescribed opioid medications in reliance on Manufacturers' statements. Manufacturers cite *Teamsters Local 237 Welfare Fund, et al., v. AstraZeneca Pharmaceuticals LP and Zeneca, Inc.*¹⁰ in support of their argument that simply pleading deceptive advertising to the public generally is insufficient.¹¹ Manufacturers assert that ultimately there is no connection between the alleged misstatements and the harm to the State. Any misstatement is simply too attenuated to establish causation. Manufacturers argue that there is no fraud on the market. Further, as third-party payors, Manufacturers cannot be forced to cover costs incurred by the State because the State is not an insurer.

¹⁰ 2015 WL 4111826 (Del. Super.).

¹¹ *Id.* at *8.

Manufacturers offer for support *State of Sao Paulo of Federative Republic of Brazil v. American Tobacco Co.*,¹² a case in which a municipality sought to recover medical expenses supposedly incurred as a result of its citizens' increased use of tobacco products.¹³ Manufacturers ask the Court to adopt the reasoning in *Sao Paulo*, specifically that it would be "both unfair and unsound policy"¹⁴ to allow a government to sue in its capacity as health care insurer or provider, and to pursue claims on which its injured citizens, had they sued directly, might not be entitled to recover. Manufacturers assert that this type of claim is something that the legislature should address and that the government should not be able to circumvent the burden of proving individual claims.

This Court finds *Sao Paulo* distinguishable. The plaintiffs in *Sao Paulo* were foreign governments, not United States municipalities. As such, the plaintiffs lacked standing to sue as *parens patriae*.¹⁵ The Court finds this distinction crucial in determining whether or not the State has standing in this case to sue in its capacity as *parens patriae*.

In support of the lack of causation argument, Manufacturers cite *Ashley County, Arkansas v. Pfizer Incorporated*.¹⁶ In *Ashley*, Arkansas counties brought

¹² 919 A.2d 1116 (D. Del. 2007).

¹³ *Id.*

¹⁴ *Id.* at 1123.

¹⁵ *Id.* at 1122.

¹⁶ 552 F.3d 659 (8th Cir. 2009).

an action against manufacturers and distributors of over-the-counter cold and allergy medications containing ephedrine or pseudoephedrine.¹⁷ The counties sought damages under the Arkansas Deceptive Trade Practices Act and the Arkansas crime victims civil liability statute, and under theories of public nuisance and unjust enrichment.¹⁸ The court found that the defendants did not proximately cause plaintiffs' damages and dismissed the claim because "the Counties cite[d] no case, federal or state, that recognizes a cause of action available to a government entity to recover against pharmaceutical manufacturers for the legal sale of products containing pseudoephedrine based on the subsequent use of the product in the manufacture of methamphetamine."¹⁹

Manufacturers also argue that the State has failed to allege injury. Manufacturers contend that the State has failed to identify any prescription received by a patient that ultimately caused injury to the State. Further, Manufacturers argue that the State is only able to make broad allegations as to all Manufacturers, and cannot single out any wrongdoing by any individual Manufacturer. Manufacturers also argue that the State's claims are barred by the derivative-injury rule, municipal cost recovery rule, and economic loss doctrine.

¹⁷ *Id.* at 670.

¹⁸ *Id.*

¹⁹ *Id.* at 673.

The State Has Stated Prima Facie Claims Against Manufacturers

The Court finds that the State has met the notice pleading requirements as to its claims against Manufacturers. Under Delaware's notice pleading requirements, a plaintiff need only "state a short and plain statement of the claims showing that the pleader is entitled to relief."²⁰ The State has met this burden by putting the Manufacturers on notice of its claims of misrepresentations ("low risk" of addiction and understated risk) made in literature and during training. The State plead its claims with sufficient particularity to allow the case to move forward. The State's allegations of labeling inconsistent with FDA approvals ("pseudoaddiction," softening and minimization) are sufficient to survive dismissal on the grounds of federal preemption. Therefore, Manufacturers' Motion to Dismiss must be denied.

Distributors

State's Allegations

The State argues that Distributors have common law, statutory, and regulatory duties to act reasonably as distributors of opioids. Specifically, the State claims that Distributors have a duty to prevent opioid diversion. The State

²⁰ Super. Ct. Civ. R. 8(a).

cites several statutes and regulations which, it claims, establish relevant duties.²¹

The State claims that the Delaware Controlled Substances Act (“CSA”) “requires distributors of controlled substances to take precautions to ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels.”²² The State claims that Delaware law has certain registration requirements for Distributors, and that in order to distribute in Delaware, the Distributors must “establish, maintain, and adhere to written policies and procedures for: identifying, records, and reporting losses or thefts” and have written policies for “reporting criminal or suspected criminal activities involving the inventory of a drug or drugs.”²³ The State makes clear that it is not asserting a cause of action under these laws, but rather, is using the laws to argue that there are established, industry-wide duties.

The State alleges that Distributors have the knowledge and expertise to identify issues relating to diversion and know how to minimize the risk of diversion. The State claims that Distributors have acknowledged these duties by making “statements assuring the public they recognize their duty to curb the opioid

²¹ Delaware’s Uniform Controlled Substances Act (16 *Del. C.* § 4701); Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0); and “numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances.” Compl. ¶ 95.

²² Compl. ¶ 103.

²³ Compl. ¶ 104-05 (quoting 24 *Del. Admin. C.* § 2500-8).

epidemic.”²⁴ The State claims that despite acknowledging and understanding their duties to prevent diversion, Distributors have violated those duties. The State asserts that Distributors have failed to identify suspicious orders,²⁵ which could have led to the discovery and prevention of diversion.

The Drug Enforcement Agency (“DEA”) supposedly has provided guidance on how to deal with suspicious orders. Since 2006, the DEA has briefed pharmaceutical distributors regarding “legal, regulatory, and due diligence responsibilities.”²⁶ The DEA has pointed out the “red flags distributors should look for to identify potential diversion.”²⁷ The DEA provided further information at conferences and in subsequent publications. The State claims that because Distributors have been educated on drug diversion, they have been put on notice of the problem of opioid diversion and the solution. Despite being put on notice, Distributors allegedly failed to prevent or address this issue.

The State argues that Distributors have negligently or recklessly allowed diversion. The State, as a basis for this allegation, points out that Distributors’ conduct has resulted “numerous civil fines and other penalties recovered by government agencies – including actions by the DEA related to violations of the

²⁴ Compl. ¶ 141.

²⁵ The State describes these orders as unusually large or frequent orders.

²⁶ Compl. ¶ 134.

²⁷ Compl. ¶ 134.

[Federal Controlled Substances Act].”²⁸ The State claims that Distributors have engaged in a consistent nationwide pattern and practice of illegally distributing opioids by allowing diversion to occur.

In sum, the State claims that the Distributors had duties to prevent opioid diversion, acknowledged and understood those duties, and violated those duties, resulting in injury to the State.

Distributors’ Response

Distributors argue that the State has failed to plead a cognizable injury under Delaware law. Distributors assert that the State cannot recover damages belonging to individuals who allegedly have been personally injured by opioid addiction. Distributors argue that the State cannot recover on the basis of these indirect injuries.²⁹ Distributors further argue that the State may not recover the costs of normal public services. In support of this position, Distributors cite *Baker v. Smith & Wesson Corporation*,³⁰ in which the Court stated: “[P]ublic expenditures made in the performance of governmental functions are not recoverable from a tortfeasor in the absence of a specific statute.”³¹

²⁸ Compl. ¶ 145.

²⁹ See *State of Sao Paulo of Federative Rep. of Braz. v. Am. Tobacco Co.*, 919 A.2d 1116, 1123 (Del. 2007)(“State may not bring a direct action to seek damages for others’ injuries without standing in their shoes as a subrogee”).

³⁰ 2002 WL 31741522 (Del. Super.).

³¹ *Id.* at *4.

Distributors argue that the State has failed to allege a negligence claim. Specifically, Distributors argue that they do not owe a duty to the State to report or halt shipment of “suspicious” orders. Distributors maintain that there is no common law or statutory duty to report these orders. Distributors also contend that there is no duty to the State because the State is not the customer. Distributors claim that their duties are solely to their customer, the pharmacies. Distributors assert that they act merely as middlemen between manufacturers and pharmacies, and that their responsibility is to take and fill orders. Distributors claim that the State has failed to allege that Distributors made any specific misrepresentations to pharmacies.

The State Has Stated Claims Against Distributors

The Court finds that Distributors’ duties are not limited to pharmacies.

Pursuant to 6 *Del. C.* § 2513:

(a) The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent *that others rely upon* such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice... (*emphasis added*).

Because the language of the statute contemplates general reliance, the Court finds that the State need not limit its claims to misrepresentations made directly to

pharmacies.

Drug diversion is a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use. The State claims that a purpose of the Delaware Consumer Fraud Act is to prevent diversion, and under this statute, Distributors have a duty to prevent diversion. Distributors maintain that the State's claims are barred by the safe harbor provided in 6 *Del. C.* § 2513 which states:

(b) This section shall not apply:

(2) To any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission...

The Court finds that whether or not Distributors complied with “rules and regulations” cannot be determined without further discovery. The Court cannot find, as a matter of law, that Distributors fall within in this safe harbor provision at this stage in the litigation.

Distributors rely on *Baker*³² to support the proposition that a municipality may not recover for its citizens' injuries. In *Baker*, the Mayor of Wilmington, on behalf of the City, sued several handgun manufacturers.³³ The lawsuit was part of a nationwide effort to force the handgun industry to make its products safer and to

³² 2002 WL 31741522 (Del. Super.).

³³ *Id.* at *1.

reduce gun violence. The plaintiffs in *Baker* were not the direct victims of injuries caused by firearms. The Court in *Baker* considered whether the City of Wilmington could recover the costs of municipal services, including police work and emergency response, in the absence of claims brought by direct victims. The issue was “whether the common law prohibition on municipalities recovering costs from tortfeasors...is the law in Delaware.”³⁴ The Court granted the defendant’s motion to dismiss, stating that “the court will not twist a jury trial involving municipal costs into a wildly expensive referendum on handgun control. The Mayor and the City must find another means to their ends.”³⁵

The Court finds that the municipal cost recovery rule does not apply in this case. In five separate courts, and in the multi-district federal litigation based in Ohio, judges have rejected the notion that the municipal cost recovery rule bars recovery for public costs. These courts reasoned that when the alleged conduct is ongoing and persistent (as opposed to a one-time event), the rule may be suspended. The Court finds that the conduct in this case is continuous. Thus, the municipal cost recovery rule does not apply.

Under 16 *Del. C.* § 4733, manufacturers, distributors, and pharmacies must register and be licensed in order to dispense opioid medications. The applicant

³⁴ *Id.*

³⁵ *Id.* at *7.

must have an underlying professional license in the State. The Secretary of State may deny registration to an applicant if the Secretary “determines that the issuance of that registration would be inconsistent with the public interest.”³⁶ The statute lists eight factors that the Secretary shall consider when determining whether an issuance of a registration would be inconsistent with the public interest:

- (1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels;
- (2) Compliance with applicable federal, state and local law, including but not limited to such requirements as having a license to practice as a practitioner or having documented training and continuing education as a drug detection animal trainer;
- (3) Any convictions of the applicant under any federal and state laws relating to any controlled substance;
- (4) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;
- (5) Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
- (6) Suspension or revocation of the applicant's federal registration to manufacture, distribute, prescribe, dispense or research controlled substances as authorized by federal law;
- (7) Any professional license disciplined in any jurisdiction; and
- (8) Any other factors relevant to the public interest.³⁷

The State argues that this statute imposes on Distributors (and Pharmacies) a duty to report, and that a breach of that duty could result in a revocation of license and registration. The State has not alleged any claims under this statute, but argues

³⁶ 16 Del. C. § 4733(a).

³⁷ *Id.*

that Section 4733 creates a well-established duty to report in the opioid industry.

The Court finds that Section 4733 does not create a cause of action.

However, the statute may be evidence of a standard of care.

Delaware recognizes the traditional “but for” definition of proximate causation.³⁸ “Most simply stated, proximate cause is [defined in Delaware as] that direct cause without which the accident would not have occurred.”³⁹ To show proximate cause, there must be known and intentional consequences.

The State alleges that Distributors had actual or constructive knowledge that they were breaching common law duties and violating the Delaware Controlled Substances Act and Federal Controlled Substances Act. Distributors counter that any diversion and subsequent harm are intervening, superseding causes that extinguish their liability. A superseding cause is a new and independent act that breaks the causal connection between the original tortious conduct and the injury.⁴⁰ However, if the intervening negligence of a third party was reasonably foreseeable, the original tortfeasor is liable for negligence because the causal connection between the original tortious act and the resulting injury remains unbroken.⁴¹

³⁸ See *Duphily v. Delaware Electric Cooperative, Inc.*, 662 A.2d 821, 828 (Del. 1995)(citing *Laws v. Webb*, 658 A.2d 1000 (Del. 1995)); *Moffitt v. Carroll*, 640 A.2d 169, 174 (Del. 1994); *Culver v. Bennett*, 588 A.2d 1094 (Del. 1991).

³⁹ *Culver v. Bennett*, 588 A.2d 1094 (Del. 1991)(quoting *Chudnofsky v. Edwards*, 208 A.2d 516 (Del. 1965)).

⁴⁰ *Duphily*, 662 A.2d at 829.

⁴¹ *Id.*

In *Ashley County, Arkansas v. Pfizer Incorporated*,⁴² the court determined that “criminal actions of the methamphetamine cooks and those further down the illegal line of manufacturing and distributing methamphetamine are ‘sufficient to stand as the cause of the injury’...and they are ‘totally independent’ of the Defendants’ actions of selling cold medicine to retail stores.”⁴³ Distributors ask this Court to apply the reasoning in *Ashley County*.

The Court finds *Ashley County* distinguishable. The State’s allegations regarding proximate cause establish a *prima facie* case of reasonable foreseeability. The intervening causes that aid diversion and subsequent illegal activities are not “totally independent” from Distributors’ conduct. The *Ashley County* court’s finding that defendants’ conduct was too attenuated to establish liability does not apply in this case.

The Court finds that the State has met its pleading requirements. Distributors’ duties are not limited to pharmacy customers. The Court cannot determine, without discovery, whether Distributors are protected by the safe harbor provision in 6 *Del. C.* § 2513. The State has set forth a *prima facie* case of reasonable foreseeability and proximate cause. Therefore, Distributors’ Motion to Dismiss the negligence and consumer fraud claims must be denied.

⁴² 552 F.3d 659 (8th Cir. 2009).

⁴³ *Id.* at 670.

The State Has Stated Claims Against Anda

Distributor Defendant Anda Pharmaceuticals, Inc. (“Anda”) has moved separately from other Distributors. Anda argues that the Complaint improperly lumps all of the Distributors together in group allegations, and that these allegations are conclusory. Anda echoes the arguments presented by other Distributors, but adds that the Complaint is not specific enough to put Anda on notice.

Superior Court Rule 9(b) requires that certain types of claims be plead with a heightened particularity. “The purpose of this Rule is to ‘(1) provide defendants with enough notice to prepare a defense; (2) prevent plaintiffs from using complaints as fishing expeditions to unearth wrongs to which they had no prior knowledge; and (3) preserve a defendant's reputation and goodwill against baseless claims.’”⁴⁴

In order to plead negligence with the requisite particularity, “a defendant must be apprised of: (1) what duty, if any, was breached; (2) who breached it, (3) what act or failure to act breached the duty, and (4) the party upon whom the act was performed.”⁴⁵ In its Complaint, the State repeatedly refers to specific statutory

⁴⁴ *Greenfield for Ford v. Budget of Delaware, Inc.*, 2017 WL 729769, at *2 (Del. Super.)(quoting *In re Benzene Litigation*, 2007 WL 625054, at *6 (Del. Super.)(citing *Stuchen v. Duty Free Int'l, Inc.*, 1996 WL 33167249, at *5 (Del. Super.))).

⁴⁵ *Myer v. Dyer*, 542 A.2d 802, 805 (Del. Super.).

and common law duties, identifies defendant groups, points out the actions or inactions Defendants allegedly committed or omitted, and claims that Defendants' conduct caused injury to the State of Delaware.

At the pleading stage, a defendant in a group of similar defendants may attempt to distinguish its behavior from other defendants.⁴⁶ When given the opportunity at oral argument to distinguish itself from other Distributors, Anda only highlighted two differences: (1) that there were no enforcement actions against Anda initiated by the DEA; and (2) that there were no allegations of specific misrepresentations, unlike those in the Complaint against Cardinal and McKesson. Anda emphasized that the State only referenced Anda specifically a few times in its Complaint.

The Court finds that there is no meaningful or substantive distinction between Anda and other Distributor defendants at this stage of the proceedings. The Court's rulings apply to Anda in the same manner as to Distributors. Anda has failed to distinguish itself from other Distributor defendants. Therefore, Anda's Motion to Dismiss must be denied.

⁴⁶ *In re Benzene Litigation*, 2007 WL 625054, at *1 (Del. Super.)(In a mass tort case, the Court allowed defendants to isolate claims among a group of defendants. The defendants moved separately to distinguish behavior, and the court treated defendants as individual movants.).

Pharmacies

State's Allegations

The State argues that Pharmacies also have a duty to prevent diversion, and that Pharmacies have breached that duty by failing to address certain “red flags” when filling prescriptions. The State claims that at “the pharmacy level, diversion occurs whenever a pharmacist fills a prescription despite having reason to believe it was not being filled for a legitimate medical purpose.”⁴⁷ The State claims:

A prescription may lack a legitimate medical purpose when a patient is either a drug dealer or opioid-dependent, seeks to fill multiple prescriptions from different doctors, travels great distances between a doctor and a pharmacy to fill a prescription, presents multiple prescriptions for the largest dose of more than one controlled substance such as opioids and benzodiazepines, or when there are other red flags surrounding the transaction.⁴⁸

The State alleges that “[o]n information and belief, Pharmacy Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably-prudent pharmacy.”⁴⁹ The State argues that Pharmacies have a duty under the Delaware CSA to take precautions to “ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels.”⁵⁰

⁴⁷ Compl. ¶ 11.

⁴⁸ Compl. ¶ 11.

⁴⁹ Compl. ¶ 189.

⁵⁰ Compl. ¶ 114.

The State also argues that Delaware's Prescription Monitoring Program ("PMP") imposes certain duties on Pharmacies. Delaware's PMP is a reporting system that aims to monitor the sale and distribution of controlled substances in the State of Delaware.⁵¹ The State claims that the PMP imposes a duty on Pharmacies to submit information related to dispensing prescription opioids. The State argues that "under Delaware law '[w]hen a [pharmacy] has a reasonable belief that a patient may be seeking a controlled substance [including opioids] for any reason other than the treatment of an existing medical condition, the dispenser shall obtain a patient utilization report regarding the patient for the preceding 12 months from the [PMP] before dispensing the prescription.'" ⁵² The State argues that Delaware law requires that "[i]f a pharmacist believes he or she has discovered a pattern of prescription abuse, the local Board of Pharmacy and the DEA must be contacted."⁵³

The State argues that despite industry-specific knowledge of the risks of opioid abuse,⁵⁴ Pharmacies breached their duties by failing to identify "red flags" and report those issues to the proper authorities.⁵⁵ The State

⁵¹ 16 *Del. C.* § 4798.

⁵² Compl. ¶ 120 (citing 16 *Del. C.* § 4798(e)).

⁵³ Compl. ¶ 131.

⁵⁴ The State argues that Pharmacies (along with other Defendants) have received extensive guidance on how to identify signs of illegal opioid use and how to prevent that use. The State claims that Pharmacies have received training from the DEA, "state pharmacy boards," and "national industry associations." Compl. ¶ 170.

⁵⁵ Compl. ¶ 186.

contends that this breach caused injury to the State of Delaware and its citizens.

Prescription Monitoring Program

Delaware has promulgated comprehensive regulation of dispensing controlled substances.⁵⁶ Section 4735(b) of Title 16 sets forth an express purpose to prevent diversion in Delaware's PMP:

(b) The Secretary, after due notice and hearing may limit, suspend, fine or revoke the registration of any registrant who:

(1) Has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels....⁵⁷

Regulation of prescription drug distribution also is contained in Delaware's Uniform Controlled Substances Act (16 *Del. C.* §§ 4701, *et seq.*), Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0 *et seq.*), code sections regarding branding of drugs (*e.g.*, 16 *Del. C.* §§ 3302, *et seq.*), and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances. These provisions provide strict controls and requirements throughout the opioid distribution chain. Delaware law also incorporates and references Federal law regarding the marketing, distribution, and

⁵⁶ 16 *Del. C.* §§ 4701 *et seq.*

⁵⁷ 16 *Del. C.* § 4735(b)(1).

sale of prescription opioids, including the Federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C §§ 321 *et seq.*

Delaware's Uniform Controlled Substances act is administered by the Secretary of State:

The Secretary shall administer this chapter. Except as otherwise provided in this chapter, the Secretary may delete or reschedule substances enumerated in the schedules of controlled substances only if:

- (1) Such substances have been deleted from or rescheduled within the federal schedules of controlled substances by the Attorney General of the United States pursuant to 21 USC § 811, *et seq.*; and
- (2) The findings required by this chapter for placement of substances in the schedules of controlled substances have been made.⁵⁸

Pharmacies' Response

Pharmacies argue that the PMP administration by Delaware's Secretary of State has exclusive jurisdiction over the regulation of prescription sales. Thus, no negligence claims may be brought by the State. However, Pharmacies concede: that the State has authority to prosecute criminal conduct; that the PMP does not prohibit medical negligence claims; and that common law negligence claims are possible. If negligence results in injury to a patient receiving a prescription, all

⁵⁸ 16 Del. C. § 4711.

“red flags” are coextensive with statutory and regulatory reporting obligations.

Pharmacies proffer *Doe v. Bradley*⁵⁹ in support of their argument that statutory duties to report misconduct do not give rise to common law negligence claims. In *Doe v. Bradley*, the Court considered “the scope of a physician's duty to report to appropriate authorities that another physician might be engaged in conduct that could endanger the health, welfare or safety of that physician's patients or the public at large.”⁶⁰ The Court found that the “[p]laintiffs’ complaint did not allege facts that would allow the court to impose a common law duty upon the medical society defendants to prevent Dr. Bradley from causing harm to the [p]laintiffs.”⁶¹ Pharmacies argue that under *Doe v. Bradley*, the regulatory scheme and enforcement procedures under Delaware law prohibit a private cause of action.

The State Has Not Stated a Claim Against Pharmacies

Delaware law requires that a medical negligence claim be accompanied by an Affidavit of Merit:

(a) No health-care negligence lawsuit shall be filed in this State unless the complaint is accompanied by:

(1) An affidavit of merit as to each defendant signed by an expert witness, as defined in § 6854 of this title, and accompanied by a current curriculum vitae of the

⁵⁹ 2011 WL 290829 (Del. Super.).

⁶⁰ 2011 WL 290829, at *1.

⁶¹ *Id.* at *4.

witness, stating that there are reasonable grounds to believe that there has been health-care medical negligence committed by each defendant....⁶²

To the extent that the State's claims fall within the definition of medical negligence, the Complaint against Pharmacies must be dismissed without prejudice to provide the State an opportunity to obtain an Affidavit of Merit.

The Court finds that the remaining allegations against Pharmacies – breaches of duties to prevent diversion – are entirely speculative and conclusory. Additionally, Delaware's comprehensive pharmacy regulatory scheme and enforcement procedures, as well as federal regulations, preempt the claims alleged in the Complaint. Therefore, Pharmacies' Motion to Dismiss must be granted. The dismissal is without prejudice as to claims sounding in medical negligence, to allow the State an opportunity to submit an Affidavit of Merit.

NUISANCE

Under Delaware law, a public nuisance is "activity which produces some tangible injury to neighboring property or persons coming into contact with it and which a court considers to be objectionable under the circumstances."⁶³

Distributors argue that the State's public nuisance claim is not cognizable

⁶² 16 Del. C. § 6853(a).

⁶³ *Patton v. Simone*, 1992 WL 398478, at *9 (Del. Super.)(citing *State v. Hill*, 167 A.2d 738, 741 (Del. Ch. 1961)).

under Delaware law. Distributors assert that Delaware Courts do not recognize products-based public nuisance claims, only property-based nuisance claims. Distributors rely on *Sills v. Smith & Wesson Corporation*⁶⁴ to support this position.⁶⁵ Distributors argue that the State has not identified or alleged a public right with which Distributors have interfered, claiming this as an essential element to a nuisance claim.

In *Sills v. Smith & Wesson Corporation*,⁶⁶ the Mayor of Wilmington sued twelve handgun manufacturers and three trade associations to recover money damages incurred by the City in connection with the design, marketing, and advertising of handguns. One of the nine counts alleged was a nuisance claim. The complaint alleged that “governmental entities may recover direct costs associated with protecting their citizens in the ‘abatement of a public nuisance.’”⁶⁷ The Court stated that “Delaware has yet to recognize a cause of action for public nuisance based upon products. Delaware public nuisance claims have been limited to situations involving land use. While no express authority exists requiring public

⁶⁴ 2000 WL 33113806 (Del. Super.).

⁶⁵ *Sills v. Smith & Wesson Corp.*, 2000 WL 33113806 (Del. Super.)(holding that Delaware law does not recognize products-based nuisance claims).

⁶⁶ 2000 WL 33113806 (Del. Super.).

⁶⁷ *Id.* at *2 (citing *City of Evansville v. Kentucky Liquid Recycling, Inc.*, 604 F.2d 1008, 1017 (7th Cir. 1979), *cert. denied*, 444 U.S. 1025 (1980)(costs of abating toxic waste public nuisance are recoverable); *U.S. v. Occidental Chem. Corp.*, 965 F.Supp. 408, 412–413 (W.D.N.Y. 1997) (exercise of police power to protect public health in abating toxic waste public nuisance are recoverable)).

nuisance claims be restricted to those based on land use, Delaware courts remain hesitant to expand public nuisance.”⁶⁸ The Court held that there was “no independent claim for public nuisance” and refused to recognize a public nuisance claim for products.⁶⁹

Other jurisdictions also have refused to allow products-based public nuisance claims. There is a clear national trend to limit public nuisance to land use.⁷⁰

On December 28, 2018, the State submitted to the Court supplemental authority related to briefing on Defendants’ Motions to Dismiss, attaching an opinion issued by MDL Judge Dan Aaron Polster of the United States District Court for the Northern District of Ohio. This Court concurs with Judge Polster as

⁶⁸ *Id.* at *7.

⁶⁹ *Id.*

⁷⁰ See, e.g., *Tioga Public School Dist. No. 15 of Williams County, State of N.D. v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993) (“to interpret the nuisance statute in the manner espoused by Tioga would in effect totally rewrite North Dakota tort law”); *State v. Lead Industries, Ass’n, Inc.*, 951 A.2d 428, 456 (R.I. 2008) (“[t]he law of public nuisance never before has been applied to products, however harmful”); *In re Lead Paint Litig.*, 924 A.2d 484, 505 (N.J. 2007) (“were we to permit these complaints to proceed, we would stretch the concept of public nuisance far beyond recognition and would create a new and entirely unbounded tort antithetical to the meaning and inherent theoretical limitations to the tort of public nuisance”); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004) (“there is no authority for the unprecedented expansion of the concept of public rights to encompass the right asserted by plaintiffs...the plaintiff’s claim does not meet all of the required elements of a public nuisance action”); *People ex re. Spitzer v. Sturm, Ruger & Co., Inc.*, 761 N.Y.S. 2d 192, 196 (N.Y. App. Div. 2003) (“giving a green light to a common-law public nuisance cause of action today will, in our judgment, likely open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities”).

to the vast majority of his conclusions. However, the Court finds this supplemental authority distinguishable from the State's case regarding the public nuisance claim.

Judge Polster's Opinion discusses in great detail Ohio legislative history relating to product liability and nuisance claims. The Opinion determined that "in light of the legislative history, the Court finds it at least plausible, if not likely, that the 2005 and 2007 Amendments to the OPLA intended to clarify the definition of 'product liability claim' to mean 'a claim or cause of action [including any common law negligence or public nuisance theory of product liability...] that is asserted in a civil action...that seeks to recover compensatory damages...for [harm]....'"⁷¹

There is no comparable legislative history in Delaware.

The State only has alleged a public nuisance claim. The State has not alleged a product liability claim, nor has it asked the Court to determine whether Delaware product liability law contemplates a public nuisance claim. In Delaware, public nuisance claims have not been recognized for products.⁷²

The State has failed to allege a public right with which Defendants have interfered. A defendant is not liable for public nuisance unless it exercises control

⁷¹ *In re National Prescription Opiate Litigation*, No. 1:17-md-2804 (6th Cir. 2018), <http://courtweb.pamd.uscourts.gov/courtwebsearch/ndoh/BOTExQ3LV4.pdf>.

⁷² *Sills v. Smith & Wesson Corp.*, 2000 WL 33113806, at *7 (Del. Super.).

over the instrumentality that caused the nuisance at the time of the nuisance.⁷³ The State has failed to allege control by Defendants over the instrumentality of the nuisance at the time of the nuisance. Thus, all Defendants' Motions to Dismiss the nuisance claims must be granted.

CIVIL CONSPIRACY

To establish a valid claim for civil conspiracy, a plaintiff must prove: “(1) A confederation or combination of two or more persons; (2) An unlawful act done in furtherance of the conspiracy; and (3) Actual damage.”⁷⁴ “In Delaware, ‘civil conspiracy is not an independent cause of action...it must arise from some underlying wrong.’”⁷⁵

The State argues that Manufacturers “have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids.”⁷⁶ The State argues that “[w]ithout Manufacturer Defendants’ misrepresentations, which created demand, Distributor Defendants would not have been able to sell to Pharmacy Defendants the increasing number of

⁷³ *Patton v. Simone*, 1992 WL 183064, at *13 (Del. Super.).

⁷⁴ *Johnson v. Preferred Professional Ins. Co.*, 91 A.3d 994, 1014 (Del. Super.)(citing *Nicolet, Inc. v. Nutt*, 525 A.2d 146, 149–50 (Del. 1987)(citing *McLaughlin v. Copeland*, 455 F.Supp. 749, 752 (D.Del. 1978), *aff’d*, 595 F.2d 1213 (3d Cir. 1979))).

⁷⁵ *Id.* at 1014 (citing *Ramunno v. Cawley*, 705 A.2d 1029, 1030 (Del. 1998)).

⁷⁶ Compl. ¶ 303.

orders of prescription opioids for non-medical purposes throughout Delaware.”⁷⁷

The State asserts that “[w]ithout Distributor Defendants’ supply of prescription opioids, Pharmacy Defendants would not have been able to fill and dispense the increasing number of orders of prescription opioids for non-medical purposes throughout Delaware.”⁷⁸ The State alleges that this chain of conduct lead to damages suffered by the State of Delaware and its citizens.

“There is no such thing as a conspiracy to commit negligence or, more precisely, to fail to exercise due care.”⁷⁹ However, in *Nicolet, Inc. v. Nutt*,⁸⁰ the Delaware Supreme Court found allegations of intentional misrepresentation of fraudulent concealment sufficient to support the plaintiffs’ claim that a manufacturer participated in an industry-wide conspiracy to conceal the health hazards of asbestos.⁸¹

In order to allege a *prima facie* case of fraudulent concealment, a plaintiff must show: “(1) deliberate concealment of a material fact or silence in the face of a duty to speak; (2) scienter; (3) intent to induce reliance upon the concealment; (4) causation; and (5) resulting damage.”⁸² In *Nicolet*, the Delaware Supreme Court

⁷⁷ Compl. ¶ 305.

⁷⁸ Compl. ¶ 306.

⁷⁹ *Szczerba v. American Cigarette Outlet, Inc.*, 2016 WL 1424561, at *3 (Del. Super.)(citing *Anderson v. Airco, Inc.*, 2004 WL 2827887 (Del. Super.)(citing *Ryan v. Eli Lilly & Co.*, 514 F.Supp. 1004, 1012 (D.S.C.1981))).

⁸⁰ 525 A.2d 146 (Del. 1987).

⁸¹ *Id.* at 149.

⁸² *Szczerba*, 2016 WL 1424561, at *3 (citing *Nicolet*, 525 A.2d at 149-50).

found that the plaintiffs met these elements, reasoning:

[P]laintiffs claim ... the conspiracy, which allegedly included [defendant], caused “to be positively asserted to plaintiffs in a manner not warranted by the information possessed by said defendants, ... that it was safe ... to work in close proximity to [the] [asbestos] materials” and ... suppressed “medical and scientific data and other knowledge, causing plaintiffs to be and remain ignorant thereof.” The complaint clearly alleges scienter in that the participants “knowingly and willfully conspired” in the scheme ... [and] alleges an intent ... to induce ... reliance on false or incomplete material facts. In our opinion these allegations are sufficient to state a tort claim based on a theory of fraudulent concealment.⁸³

In this case, the Court finds that the State has not adequately alleged in its Complaint that Defendants engaged in a civil conspiracy similar to the allegations in *Nicolet*. The State has merely alleged parallel conduct by Defendants, making no claims that “the participants ‘knowingly and willfully conspired’ in the scheme”⁸⁴ in order to induce reliance. The State has not alleged that the Defendants intended to conspire, but merely stated at oral argument that Defendants attended the same conferences. There are no allegations of a concerted action, an agreement to commit an underlying wrong, awareness of an agreement, or action in accordance with that agreement. The State argues that “Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants need not have expressly agreed to this course of action; concerted conduct itself is sufficient.”

⁸³ *Nicolet*, 525 A.2d at 149.

⁸⁴ *Id.*

This argument is not supported by Delaware law.

The Civil Conspiracy claims are hereby dismissed without prejudice. The claims may be added if evidence supporting a conspiracy surfaces during discovery.

UNJUST ENRICHMENT

Delaware law defines unjust enrichment as “the unjust retention of a benefit to the loss of another, or the retention of money or property of another against the fundamental principles of justice or equity and good conscience.”⁸⁵ Unjust enrichment requires the following: (1) an enrichment; (2) an impoverishment; (3) a relation between the enrichment and the impoverishment; (4) the absence of justification; and (5) the absence of a remedy provided by law.⁸⁶

Under Delaware law, unjust enrichment is not a stand-alone claim in Superior Court. The claim must be brought in the Court of Chancery. In this Court, unjust enrichment may be asserted as a possible measure of damages. Therefore, the unjust enrichment claim must be dismissed.

⁸⁵ *Incyte Corporation v. Flexus Biosciences, Inc.*, 2017 WL 7803923, at *4 (Del. Super.)(citing *Nemec v. Shrader*, 991 A.2d 1120, 1130 (Del. 2010)).

⁸⁶ *See Nemec v. Shrader*, 991 A.2d 110, 1130 (Del. 2010).

ENDO PHARMACEUTICALS INC.'S MOTION TO STRIKE

Endo argues that to the extent that the State relies on references to a 2016 Assurance of Discontinuance (AOD) between the New York Attorney General and Endo, those allegations should be stricken or, at a minimum, cannot form the basis of the State's claims. Endo also argues that the AOD was made without Endo admitting to any of the findings of the New York Attorney General's investigation. The parties allegedly agreed that the AOD was not intended for use by any third party in any other proceeding and is not intended, and should not be construed, as an admission by Endo of any liability or finding set forth hererin."⁸⁷ Endo argues that the State is trying to use the settlement against Endo. Endo claims that many courts have stricken as immaterial and impertinent allegations that refer to or are derived from settlements and other preliminary or non-adjudicated proceedings, including governmental investigations.

The State claims that it is only using two findings from the New York Attorney General's investigation, which Endo did not admit. Further, the settlement is not an admission by Endo, but the statements quoted by the State in its Complaint are the New York Attorney General's findings, and the State has a right to use them. The State contends that it is not using the findings to establish

⁸⁷ Assurance of Discontinuance ¶¶ 54, 67 (Endo requested in its Motion to Dismiss that the Court take judicial notice of the AOD, an executed copy of which is available on the NYAG's website.); See https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

Endo's liability, but to help refute Endo's contention that the State has not stated a claim. The State argues that pleadings are not evidence of liability and are more properly a subject of a motion *in limine*.⁸⁸

When ruling on a motion to strike, the Court considers: (1) whether the challenged averments are relevant to an issue in the case; and (2) whether they are unduly prejudicial.⁸⁹ "Motions to strike are not favored and are granted sparingly, and then only if clearly warranted, with doubt being resolved in favor of the pleading, and objectionable matter will be stricken only if it is clearly shown to be unduly prejudicial."⁹⁰

The Court finds that the matters objected to in Endo's motion are relevant and have not been shown to be unduly prejudicial. Therefore, Endo's Motion to Strike Paragraph 83 of the Complaint must be denied.

⁸⁸ The State proffers *Johnson v. M&M*, 242 F.R.D. 187, 190 (D. Conn. 2007) ("a complaint is not submitted to the jury" and "whether evidence of the prior investigations will be admissible at trial is an issue to be resolved at a later stage").

⁸⁹ See *Shaffer v. Davis*, 1990 WL 81892, at *4 (Del. Super.) (citing *Pack & Process, Inc. v. Celotex Corp.*, 503 A.2d 646, 660-61 (Del. Super. 1990)).

⁹⁰ *Pack & Process, Inc. v. Celotex Corp.*, 503 A.2d 646, 660-61 (Del. Super. 1985).

CONCLUSION

The Court finds that the State of Delaware has established a *prima facie* case for Negligence and Consumer Fraud against the Manufacturer Defendants, Anda Pharmaceuticals, and the Distributor Defendants. However, the State of Delaware has not demonstrated a *prima facie* case for Negligence and Consumer Fraud claims against the Pharmacy Defendants. **Therefore, Manufacturer Defendants', Distributor Defendants', and Anda Pharmaceuticals' Motions to Dismiss the Negligence and Consumer Fraud claims are hereby DENIED. Pharmacy Defendants' Motion to Dismiss the Negligence and Consumer Fraud claims is hereby GRANTED.**

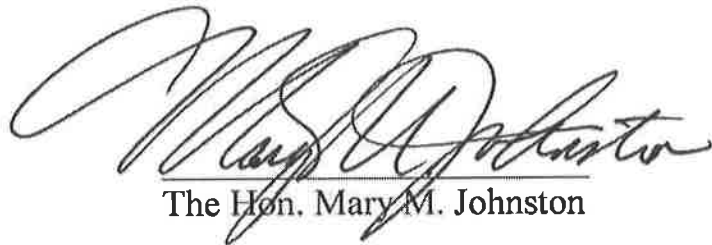
The Court finds that the State of Delaware's nuisance claims fail as a matter of law. **Therefore, all Motions to Dismiss the Nuisance claims are hereby GRANTED.**

The Court finds that the State of Delaware has failed to adequately plead its civil conspiracy claim because the State only asserts parallel conduct by Defendants and has failed to establish a *prima facie* case involving concerted action, agreement, awareness of the agreement, and action in accordance with that agreement. **Therefore, all Motions to Dismiss the Civil Conspiracy claims are hereby GRANTED, without prejudice. Claims for Civil Conspiracy may be added if such evidence surfaces during discovery.**

The Court finds that the State of Delaware's unjust enrichment claim is not a stand-alone claim at law. This claim must be brought in the Court of Chancery. Unjust enrichment may be asserted as a possible measure of damages. **Therefore, all Motions to Dismiss the Unjust Enrichment claims are hereby GRANTED.**

The Court finds that the matter objected to in Endo Pharmaceutical's Motion to Strike Paragraph 83 of the Complaint has not been shown to be unduly prejudicial. **Therefore, Endo Pharmaceutical's Motion to Strike Paragraph 83 of the Complaint is hereby DENIED.**

IT IS SO ORDERED.



The Hon. Mary M. Johnston

EXHIBIT 1

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

STATE OF DELAWARE, <i>ex rel.</i>)	
KATHLEEN JENNINGS, Attorney)	
General of the State of Delaware,)	
)	
Plaintiff,)	C.A. No. N18C-01-223 MMJ CCLD
)	
v.)	
)	
PURDUE PHARMA L.P.; PURDUE)	
PHARMA INC.; THE PURDUE)	
FREDERICK COMPANY; ENDO)	
HEALTH SOLUTIONS INC.;)	
ENDO PHARMACEUTICALS INC.;)	
MCKESSON CORPORATION;)	
CARDINAL HEALTH INC.;)	
AMERISOURCEBERGEN)	
CORPORATION; ANDA)	
PHARMACEUTICALS, INC.; H.D.)	
SMITH, LLC; CVS HEALTH)	
CORPORATION; and WALGREENS)	
BOOTS ALLIANCE, INC.,)	
)	
Defendants.)	

Submitted: November 15, 2018

Decided: February 4, 2019

Upon Defendants' Motions to Dismiss and Motion to Strike

Ryan P. Newell, Esq., Shaun Michael Kelly, Esq., Kyle Evans Gay, Esq., Connolly Gallagher, LLP, Wilmington, Delaware; Richard W. Fields, Esq., Fields PLLC, Washington, District of Columbia; Scott W. Gilbert, Esq., Richard Shore, Esq. (Argued), Mark A. Packman, Esq., Jenna A. Hudson, Esq. (Argued), Michael B. Rush, Esq. (Argued), Monique T. Abrishami, Esq., Richard J. Leveridge, Esq., Gilbert LLP, Washington, District of Columbia; Kathleen Jennings, Attorney General, Michael Vild, Esq., Michelle Whalen, Esq., Delaware Department of Justice, *Attorneys for the State of Delaware.*

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JOHNSTON, J.

PROCEDURAL CONTEXT

The State of Delaware (“State”), ex rel. Kathleen Jennings,¹ Attorney General of the State of Delaware, brought this suit seeking compensatory, punitive, and other damages, as well as restitution, disgorgement, and civil penalties.

Defendants are: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Endo Health Solutions Inc., and Endo Pharmaceuticals Inc.

(collectively, “Manufacturers”); McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda Pharmaceuticals, Inc., and H. D. Smith, LLC (collectively, “Distributors”); and CVS Health Corporation and Walgreens Boots Alliance, Inc. (collectively, “Pharmacies”).

As to the Manufacturers, the State argues that Manufacturers have duties to

¹ At the time the pending motions were heard, Matthew P. Denn was Attorney General.

disclose accurately the risks associated with opioid medications, specifically, the high risk of addiction and subsequent misuse. The State contends that Manufacturers misrepresented those risks through multi-million-dollar advertising campaigns, and inaccurately claimed that those who were showing signs of addiction were not actually addicted. The State argues that these misstatements were targeted for maximum effect and to a specific audience. The State contends that Manufacturers knew or should have known that their statements were false and misleading. Because they knew the statements were misleading, Manufacturers violated their duties to disclose accurately the risks of using purportedly highly dangerous opioid medications.

As to Distributors, the State argues that Distributors have duties to actively prevent opioid diversion.² The State asserts that both Delaware and federal law have established the duties of care that Distributors must follow. The State argues that, as evidenced by prior regulatory actions against Distributors for failing to prevent diversion, Distributors have violated their duties.

Similarly, as to Pharmacies, the State argues that Pharmacies have duties to prevent opioid diversion and to report any suspicious orders. The State alleges that Pharmacies repeatedly have failed to report suspicious orders made obvious to

² Drug diversion refers to the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

them by certain “red flags,” such as unusually large orders, repetitive orders, and improperly filled orders. The State argues that Pharmacies have violated their duties owed to the State, as evidenced by prior regulatory actions against Pharmacies.

The State argues that Defendants’ collective misconduct has harmed and continues to harm the State of Delaware and its citizens.³ The State alleges the following:

Count I: Consumer Fraud (Against Manufacturer Defendants)

Count II: Nuisance (Against Manufacturer Defendants)

Count III: Negligence (Against Manufacturer Defendants)

Count IV: Unjust Enrichment (Against Manufacturer Defendants)

Count V: Consumer Fraud (Against Distributor Defendants and Pharmacy Defendants)

Count VI: Nuisance (Against Distributor Defendants and Pharmacy Defendants)

Count VII: Negligence (Against Distributor Defendants and Pharmacy Defendants)

³ In recent years, the frequency of opioid use for both chronic pain and non-medical purposes has grown dramatically, resulting in an epidemic of prescription opioid abuse. According to the Centers for Disease Control and Prevention (“CDC”), Delaware lost 669 people to drug overdose deaths between 2014 and 2016. The alleged “main driver” of such deaths was prescription and illicit opioids.

Count VIII: Unjust Enrichment (Against Distributor Defendants and Pharmacy Defendants)

Count IX: Civil Conspiracy (Against Manufacturer Defendants, Distributor Defendants, Pharmacy Defendants).

Defendants have filed Motions to Dismiss. Manufacturers joined together to file one Motion to Dismiss. Four of the five Distributors filed Motions to Dismiss: McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation have jointly filed one motion. Anda Pharmaceuticals, Inc. has separately filed its own motion. The remaining distributor, H.D. Smith, LLC, has not joined in or filed its own motion to dismiss, but did answer the complaint. The Pharmacies jointly filed one motion to dismiss. Oral Argument was heard over two days: October 24, 2018 and November 15, 2018.

MOTION TO DISMISS STANDARD

In a Rule 12(b)(6) Motion to Dismiss, the Court must determine whether the claimant “may recover under any reasonably conceivable set of circumstances susceptible of proof.”⁴ The Court must accept as true all well-pleaded allegations.⁵

⁴ *Spence v. Funk*, 396 A.2d 967, 968 (Del.1978).

⁵ *Id.*

Every reasonable factual inference will be drawn in the non-moving party's favor.⁶ If the claimant may recover under that standard of review, the Court must deny the Motion to Dismiss.⁷

ANALYSIS

NEGLIGENCE AND CONSUMER FRAUD

The State contends that all Defendants violated statutory and common law duties, which caused injury to the State. The State's claims vary slightly as to each class of Defendant.

Manufacturers

State's Allegations

The State argues that each Manufacturer Defendant has a legal obligation under Delaware statutory and common law to exercise reasonable care in the marketing, promotion, and sale of opioids. The State argues that Manufacturers' duties are established by 16 *Del. C.* § 3302, which states: "No person shall manufacturer, sell or trade in, within this State, any article of food or drugs which

⁶ *Wilmington Sav. Fund. Soc 'v, F.S.B. v. Anderson*, 2009 WL 597268, at *2 (Del. Super.) (citing *Doe v. Cahill*, 884 A.2d 451, 458 (Del.2005)).

⁷ *Spence*, 396 A.2d at 968.

is . . . misbranded . . . within the meaning of this chapter.”⁸

The State argues that Manufacturers have breached their duties by misstating facts and by failing to disclose accurately the risks associated with the use of opioids. The State claims that Manufacturers have done this via a multi-million-dollar advertising campaign that is run through websites, promotional materials, live conferences, publications for doctors, and other vehicles. The State asserts that Manufacturers trained pharmaceutical salesmen to tell doctors that the risk of opioid addiction is less than 1%, which is contrary to Center for Disease Control (“CDC”) findings that suggest that there are significant risks of serious opioid addiction and abuse. The CDC reports that about 26% of long term users experience problems with addiction or dependence.⁹ The State claims although there are warning labels approved by the Food and Drug Administration (“FDA”) on the bottles of medication, the content in the advertising campaign is inconsistent with those warning labels in that the advertising scheme significantly minimizes

⁸ See 16 Del. C. § 3308 (“For the purposes of this chapter, a drug is deemed to be misbranded: (1) If it is an imitation of or offered for sale under the name of another drug; (2) If the contents of the package as originally put up were removed, in whole or in part, and other contents were placed in such package or if the package fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate or acetanilide, or any derivative or preparation of any such substances contained therein; (3) If its package or label bears any statement, design or device regarding such article, or the ingredients or substances contained therein which is false or misleading in any particular way; (4) If it is included in the definition of misbranding in the Federal Food, Drug and Cosmetic Act.”).

⁹ Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

the risks.

Further, the State argues that Manufacturers stated that patients who showed signs of addiction were not actually addicted to opioids. The State claims that Manufacturers published a physician education pamphlet which suggested that patients who showed signs of addiction were actually in need of more medication, a phenomenon Manufacturers refer to as “pseudoaddiction.” The State argues that “pseudoaddiction,” a term coined by a Manufacturer, is a concept rejected by the CDC because it lacks scientific evidence. The State claims that Manufacturers advocate for increasing dosages regardless of a patient’s actual prescribed dosage. The State contends that, through their web content, Manufacturers actually encourage patients, who believe they have not been prescribed an adequate dose, to seek a different doctor who will prescribe them the dose they feel they require. The State asserts that Manufacturers claim there is no risk of addiction when the dosage is increased.

The State argues that Manufacturers’ conduct amounts to a breach of duty owed to the State.

Manufacturers’ Response

Manufacturers argue first that the State’s claims are preempted because the FDA has approved opioid medications for the treatment of pain. Manufacturers

maintain that they have complied with the FDA's warning label requirements.

Manufacturers argue that the State cannot impose a duty to alter FDA-approved medicine. Further, Manufacturers assert that courts repeatedly have held that state law claims are preempted where they would require a manufacturer to make statements about safety or efficacy that are inconsistent with what the FDA has required.

Manufacturers also argue that the State has failed to allege causation. Manufacturers argue that the State has failed to identify any physician who heard the alleged misrepresentations and subsequently prescribed opioid medications in reliance on Manufacturers' statements. Manufacturers cite *Teamsters Local 237 Welfare Fund, et al., v. AstraZeneca Pharmaceuticals LP and Zeneca, Inc.*¹⁰ in support of their argument that simply pleading deceptive advertising to the public generally is insufficient.¹¹ Manufacturers assert that ultimately there is no connection between the alleged misstatements and the harm to the State. Any misstatement is simply too attenuated to establish causation. Manufacturers argue that there is no fraud on the market. Further, as third-party payors, Manufacturers cannot be forced to cover costs incurred by the State because the State is not an insurer.

¹⁰ 2015 WL 4111826 (Del. Super.).

¹¹ *Id.* at *8.

Manufacturers offer for support *State of Sao Paulo of Federative Republic of Brazil v. American Tobacco Co.*,¹² a case in which a municipality sought to recover medical expenses supposedly incurred as a result of its citizens' increased use of tobacco products.¹³ Manufacturers ask the Court to adopt the reasoning in *Sao Paulo*, specifically that it would be "both unfair and unsound policy"¹⁴ to allow a government to sue in its capacity as health care insurer or provider, and to pursue claims on which its injured citizens, had they sued directly, might not be entitled to recover. Manufacturers assert that this type of claim is something that the legislature should address and that the government should not be able to circumvent the burden of proving individual claims.

This Court finds *Sao Paulo* distinguishable. The plaintiffs in *Sao Paulo* were foreign governments, not United States municipalities. As such, the plaintiffs lacked standing to sue as *parens patriae*.¹⁵ The Court finds this distinction crucial in determining whether or not the State has standing in this case to sue in its capacity as *parens patriae*.

In support of the lack of causation argument, Manufacturers cite *Ashley County, Arkansas v. Pfizer Incorporated*.¹⁶ In *Ashley*, Arkansas counties brought

¹² 919 A.2d 1116 (D. Del. 2007).

¹³ *Id.*

¹⁴ *Id.* at 1123.

¹⁵ *Id.* at 1122.

¹⁶ 552 F.3d 659 (8th Cir. 2009).

an action against manufacturers and distributors of over-the-counter cold and allergy medications containing ephedrine or pseudoephedrine.¹⁷ The counties sought damages under the Arkansas Deceptive Trade Practices Act and the Arkansas crime victims civil liability statute, and under theories of public nuisance and unjust enrichment.¹⁸ The court found that the defendants did not proximately cause plaintiffs' damages and dismissed the claim because "the Counties cite[d] no case, federal or state, that recognizes a cause of action available to a government entity to recover against pharmaceutical manufacturers for the legal sale of products containing pseudoephedrine based on the subsequent use of the product in the manufacture of methamphetamine."¹⁹

Manufacturers also argue that the State has failed to allege injury. Manufacturers contend that the State has failed to identify any prescription received by a patient that ultimately caused injury to the State. Further, Manufacturers argue that the State is only able to make broad allegations as to all Manufacturers, and cannot single out any wrongdoing by any individual Manufacturer. Manufacturers also argue that the State's claims are barred by the derivative-injury rule, municipal cost recovery rule, and economic loss doctrine.

¹⁷ *Id.* at 670.

¹⁸ *Id.*

¹⁹ *Id.* at 673.

The State Has Stated Prima Facie Claims Against Manufacturers

The Court finds that the State has met the notice pleading requirements as to its claims against Manufacturers. Under Delaware's notice pleading requirements, a plaintiff need only "state a short and plain statement of the claims showing that the pleader is entitled to relief."²⁰ The State has met this burden by putting the Manufacturers on notice of its claims of misrepresentations ("low risk" of addiction and understated risk) made in literature and during training. The State plead its claims with sufficient particularity to allow the case to move forward. The State's allegations of labeling inconsistent with FDA approvals ("pseudoaddiction," softening and minimization) are sufficient to survive dismissal on the grounds of federal preemption. Therefore, Manufacturers' Motion to Dismiss must be denied.

Distributors

State's Allegations

The State argues that Distributors have common law, statutory, and regulatory duties to act reasonably as distributors of opioids. Specifically, the State claims that Distributors have a duty to prevent opioid diversion. The State

²⁰ Super. Ct. Civ. R. 8(a).

cites several statutes and regulations which, it claims, establish relevant duties.²¹

The State claims that the Delaware Controlled Substances Act (“CSA”) “requires distributors of controlled substances to take precautions to ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels.”²² The State claims that Delaware law has certain registration requirements for Distributors, and that in order to distribute in Delaware, the Distributors must “establish, maintain, and adhere to written policies and procedures for: identifying, records, and reporting losses or thefts” and have written policies for “reporting criminal or suspected criminal activities involving the inventory of a drug or drugs.”²³ The State makes clear that it is not asserting a cause of action under these laws, but rather, is using the laws to argue that there are established, industry-wide duties.

The State alleges that Distributors have the knowledge and expertise to identify issues relating to diversion and know how to minimize the risk of diversion. The State claims that Distributors have acknowledged these duties by making “statements assuring the public they recognize their duty to curb the opioid

²¹ Delaware’s Uniform Controlled Substances Act (16 *Del. C.* § 4701); Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0); and “numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances.” Compl. ¶ 95.

²² Compl. ¶ 103.

²³ Compl. ¶ 104-05 (quoting 24 *Del. Admin. C.* § 2500-8).

epidemic.”²⁴ The State claims that despite acknowledging and understanding their duties to prevent diversion, Distributors have violated those duties. The State asserts that Distributors have failed to identify suspicious orders,²⁵ which could have led to the discovery and prevention of diversion.

The Drug Enforcement Agency (“DEA”) supposedly has provided guidance on how to deal with suspicious orders. Since 2006, the DEA has briefed pharmaceutical distributors regarding “legal, regulatory, and due diligence responsibilities.”²⁶ The DEA has pointed out the “red flags distributors should look for to identify potential diversion.”²⁷ The DEA provided further information at conferences and in subsequent publications. The State claims that because Distributors have been educated on drug diversion, they have been put on notice of the problem of opioid diversion and the solution. Despite being put on notice, Distributors allegedly failed to prevent or address this issue.

The State argues that Distributors have negligently or recklessly allowed diversion. The State, as a basis for this allegation, points out that Distributors’ conduct has resulted “numerous civil fines and other penalties recovered by government agencies – including actions by the DEA related to violations of the

²⁴ Compl. ¶ 141.

²⁵ The State describes these orders as unusually large or frequent orders.

²⁶ Compl. ¶ 134.

²⁷ Compl. ¶ 134.

[Federal Controlled Substances Act].”²⁸ The State claims that Distributors have engaged in a consistent nationwide pattern and practice of illegally distributing opioids by allowing diversion to occur.

In sum, the State claims that the Distributors had duties to prevent opioid diversion, acknowledged and understood those duties, and violated those duties, resulting in injury to the State.

Distributors’ Response

Distributors argue that the State has failed to plead a cognizable injury under Delaware law. Distributors assert that the State cannot recover damages belonging to individuals who allegedly have been personally injured by opioid addiction. Distributors argue that the State cannot recover on the basis of these indirect injuries.²⁹ Distributors further argue that the State may not recover the costs of normal public services. In support of this position, Distributors cite *Baker v. Smith & Wesson Corporation*,³⁰ in which the Court stated: “[P]ublic expenditures made in the performance of governmental functions are not recoverable from a tortfeasor in the absence of a specific statute.”³¹

²⁸ Compl. ¶ 145.

²⁹ See *State of Sao Paulo of Federative Rep. of Braz. v. Am. Tobacco Co.*, 919 A.2d 1116, 1123 (Del. 2007)(“State may not bring a direct action to seek damages for others’ injuries without standing in their shoes as a subrogee”).

³⁰ 2002 WL 31741522 (Del. Super.).

³¹ *Id.* at *4.

Distributors argue that the State has failed to allege a negligence claim. Specifically, Distributors argue that they do not owe a duty to the State to report or halt shipment of “suspicious” orders. Distributors maintain that there is no common law or statutory duty to report these orders. Distributors also contend that there is no duty to the State because the State is not the customer. Distributors claim that their duties are solely to their customer, the pharmacies. Distributors assert that they act merely as middlemen between manufacturers and pharmacies, and that their responsibility is to take and fill orders. Distributors claim that the State has failed to allege that Distributors made any specific misrepresentations to pharmacies.

The State Has Stated Claims Against Distributors

The Court finds that Distributors’ duties are not limited to pharmacies.

Pursuant to 6 *Del. C.* § 2513:

(a) The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent *that others rely upon* such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice... (*emphasis added*).

Because the language of the statute contemplates general reliance, the Court finds that the State need not limit its claims to misrepresentations made directly to

pharmacies.

Drug diversion is a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use. The State claims that a purpose of the Delaware Consumer Fraud Act is to prevent diversion, and under this statute, Distributors have a duty to prevent diversion. Distributors maintain that the State's claims are barred by the safe harbor provided in 6 *Del. C.* § 2513 which states:

(b) This section shall not apply:

(2) To any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission...

The Court finds that whether or not Distributors complied with “rules and regulations” cannot be determined without further discovery. The Court cannot find, as a matter of law, that Distributors fall within in this safe harbor provision at this stage in the litigation.

Distributors rely on *Baker*³² to support the proposition that a municipality may not recover for its citizens' injuries. In *Baker*, the Mayor of Wilmington, on behalf of the City, sued several handgun manufacturers.³³ The lawsuit was part of a nationwide effort to force the handgun industry to make its products safer and to

³² 2002 WL 31741522 (Del. Super.).

³³ *Id.* at *1.

reduce gun violence. The plaintiffs in *Baker* were not the direct victims of injuries caused by firearms. The Court in *Baker* considered whether the City of Wilmington could recover the costs of municipal services, including police work and emergency response, in the absence of claims brought by direct victims. The issue was “whether the common law prohibition on municipalities recovering costs from tortfeasors...is the law in Delaware.”³⁴ The Court granted the defendant’s motion to dismiss, stating that “the court will not twist a jury trial involving municipal costs into a wildly expensive referendum on handgun control. The Mayor and the City must find another means to their ends.”³⁵

The Court finds that the municipal cost recovery rule does not apply in this case. In five separate courts, and in the multi-district federal litigation based in Ohio, judges have rejected the notion that the municipal cost recovery rule bars recovery for public costs. These courts reasoned that when the alleged conduct is ongoing and persistent (as opposed to a one-time event), the rule may be suspended. The Court finds that the conduct in this case is continuous. Thus, the municipal cost recovery rule does not apply.

Under 16 *Del. C.* § 4733, manufacturers, distributors, and pharmacies must register and be licensed in order to dispense opioid medications. The applicant

³⁴ *Id.*

³⁵ *Id.* at *7.

must have an underlying professional license in the State. The Secretary of State may deny registration to an applicant if the Secretary “determines that the issuance of that registration would be inconsistent with the public interest.”³⁶ The statute lists eight factors that the Secretary shall consider when determining whether an issuance of a registration would be inconsistent with the public interest:

- (1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels;
- (2) Compliance with applicable federal, state and local law, including but not limited to such requirements as having a license to practice as a practitioner or having documented training and continuing education as a drug detection animal trainer;
- (3) Any convictions of the applicant under any federal and state laws relating to any controlled substance;
- (4) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;
- (5) Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
- (6) Suspension or revocation of the applicant's federal registration to manufacture, distribute, prescribe, dispense or research controlled substances as authorized by federal law;
- (7) Any professional license disciplined in any jurisdiction; and
- (8) Any other factors relevant to the public interest.³⁷

The State argues that this statute imposes on Distributors (and Pharmacies) a duty to report, and that a breach of that duty could result in a revocation of license and registration. The State has not alleged any claims under this statute, but argues

³⁶ 16 Del. C. § 4733(a).

³⁷ *Id.*

that Section 4733 creates a well-established duty to report in the opioid industry.

The Court finds that Section 4733 does not create a cause of action.

However, the statute may be evidence of a standard of care.

Delaware recognizes the traditional “but for” definition of proximate causation.³⁸ “Most simply stated, proximate cause is [defined in Delaware as] that direct cause without which the accident would not have occurred.”³⁹ To show proximate cause, there must be known and intentional consequences.

The State alleges that Distributors had actual or constructive knowledge that they were breaching common law duties and violating the Delaware Controlled Substances Act and Federal Controlled Substances Act. Distributors counter that any diversion and subsequent harm are intervening, superseding causes that extinguish their liability. A superseding cause is a new and independent act that breaks the causal connection between the original tortious conduct and the injury.⁴⁰ However, if the intervening negligence of a third party was reasonably foreseeable, the original tortfeasor is liable for negligence because the causal connection between the original tortious act and the resulting injury remains unbroken.⁴¹

³⁸ See *Duphily v. Delaware Electric Cooperative, Inc.*, 662 A.2d 821, 828 (Del. 1995)(citing *Laws v. Webb*, 658 A.2d 1000 (Del. 1995)); *Moffitt v. Carroll*, 640 A.2d 169, 174 (Del. 1994); *Culver v. Bennett*, 588 A.2d 1094 (Del. 1991).

³⁹ *Culver v. Bennett*, 588 A.2d 1094 (Del. 1991)(quoting *Chudnofsky v. Edwards*, 208 A.2d 516 (Del. 1965)).

⁴⁰ *Duphily*, 662 A.2d at 829.

⁴¹ *Id.*

In *Ashley County, Arkansas v. Pfizer Incorporated*,⁴² the court determined that “criminal actions of the methamphetamine cooks and those further down the illegal line of manufacturing and distributing methamphetamine are ‘sufficient to stand as the cause of the injury’...and they are ‘totally independent’ of the Defendants’ actions of selling cold medicine to retail stores.”⁴³ Distributors ask this Court to apply the reasoning in *Ashley County*.

The Court finds *Ashley County* distinguishable. The State’s allegations regarding proximate cause establish a *prima facie* case of reasonable foreseeability. The intervening causes that aid diversion and subsequent illegal activities are not “totally independent” from Distributors’ conduct. The *Ashley County* court’s finding that defendants’ conduct was too attenuated to establish liability does not apply in this case.

The Court finds that the State has met its pleading requirements. Distributors’ duties are not limited to pharmacy customers. The Court cannot determine, without discovery, whether Distributors are protected by the safe harbor provision in 6 *Del. C.* § 2513. The State has set forth a *prima facie* case of reasonable foreseeability and proximate cause. Therefore, Distributors’ Motion to Dismiss the negligence and consumer fraud claims must be denied.

⁴² 552 F.3d 659 (8th Cir. 2009).

⁴³ *Id.* at 670.

The State Has Stated Claims Against Anda

Distributor Defendant Anda Pharmaceuticals, Inc. (“Anda”) has moved separately from other Distributors. Anda argues that the Complaint improperly lumps all of the Distributors together in group allegations, and that these allegations are conclusory. Anda echoes the arguments presented by other Distributors, but adds that the Complaint is not specific enough to put Anda on notice.

Superior Court Rule 9(b) requires that certain types of claims be plead with a heightened particularity. “The purpose of this Rule is to ‘(1) provide defendants with enough notice to prepare a defense; (2) prevent plaintiffs from using complaints as fishing expeditions to unearth wrongs to which they had no prior knowledge; and (3) preserve a defendant's reputation and goodwill against baseless claims.’”⁴⁴

In order to plead negligence with the requisite particularity, “a defendant must be apprised of: (1) what duty, if any, was breached; (2) who breached it, (3) what act or failure to act breached the duty, and (4) the party upon whom the act was performed.”⁴⁵ In its Complaint, the State repeatedly refers to specific statutory

⁴⁴ *Greenfield for Ford v. Budget of Delaware, Inc.*, 2017 WL 729769, at *2 (Del. Super.)(quoting *In re Benzene Litigation*, 2007 WL 625054, at *6 (Del. Super.)(citing *Stuchen v. Duty Free Int'l, Inc.*, 1996 WL 33167249, at *5 (Del. Super.))).

⁴⁵ *Myer v. Dyer*, 542 A.2d 802, 805 (Del. Super.).

and common law duties, identifies defendant groups, points out the actions or inactions Defendants allegedly committed or omitted, and claims that Defendants' conduct caused injury to the State of Delaware.

At the pleading stage, a defendant in a group of similar defendants may attempt to distinguish its behavior from other defendants.⁴⁶ When given the opportunity at oral argument to distinguish itself from other Distributors, Anda only highlighted two differences: (1) that there were no enforcement actions against Anda initiated by the DEA; and (2) that there were no allegations of specific misrepresentations, unlike those in the Complaint against Cardinal and McKesson. Anda emphasized that the State only referenced Anda specifically a few times in its Complaint.

The Court finds that there is no meaningful or substantive distinction between Anda and other Distributor defendants at this stage of the proceedings. The Court's rulings apply to Anda in the same manner as to Distributors. Anda has failed to distinguish itself from other Distributor defendants. Therefore, Anda's Motion to Dismiss must be denied.

⁴⁶ *In re Benzene Litigation*, 2007 WL 625054, at *1 (Del. Super.)(In a mass tort case, the Court allowed defendants to isolate claims among a group of defendants. The defendants moved separately to distinguish behavior, and the court treated defendants as individual movants.).

Pharmacies

State's Allegations

The State argues that Pharmacies also have a duty to prevent diversion, and that Pharmacies have breached that duty by failing to address certain “red flags” when filling prescriptions. The State claims that at “the pharmacy level, diversion occurs whenever a pharmacist fills a prescription despite having reason to believe it was not being filled for a legitimate medical purpose.”⁴⁷ The State claims:

A prescription may lack a legitimate medical purpose when a patient is either a drug dealer or opioid-dependent, seeks to fill multiple prescriptions from different doctors, travels great distances between a doctor and a pharmacy to fill a prescription, presents multiple prescriptions for the largest dose of more than one controlled substance such as opioids and benzodiazepines, or when there are other red flags surrounding the transaction.⁴⁸

The State alleges that “[o]n information and belief, Pharmacy Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably-prudent pharmacy.”⁴⁹ The State argues that Pharmacies have a duty under the Delaware CSA to take precautions to “ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels.”⁵⁰

⁴⁷ Compl. ¶ 11.

⁴⁸ Compl. ¶ 11.

⁴⁹ Compl. ¶ 189.

⁵⁰ Compl. ¶ 114.

The State also argues that Delaware's Prescription Monitoring Program ("PMP") imposes certain duties on Pharmacies. Delaware's PMP is a reporting system that aims to monitor the sale and distribution of controlled substances in the State of Delaware.⁵¹ The State claims that the PMP imposes a duty on Pharmacies to submit information related to dispensing prescription opioids. The State argues that "under Delaware law '[w]hen a [pharmacy] has a reasonable belief that a patient may be seeking a controlled substance [including opioids] for any reason other than the treatment of an existing medical condition, the dispenser shall obtain a patient utilization report regarding the patient for the preceding 12 months from the [PMP] before dispensing the prescription.'" ⁵² The State argues that Delaware law requires that "[i]f a pharmacist believes he or she has discovered a pattern of prescription abuse, the local Board of Pharmacy and the DEA must be contacted."⁵³

The State argues that despite industry-specific knowledge of the risks of opioid abuse,⁵⁴ Pharmacies breached their duties by failing to identify "red flags" and report those issues to the proper authorities.⁵⁵ The State

⁵¹ 16 *Del. C.* § 4798.

⁵² Compl. ¶ 120 (citing 16 *Del. C.* § 4798(e)).

⁵³ Compl. ¶ 131.

⁵⁴ The State argues that Pharmacies (along with other Defendants) have received extensive guidance on how to identify signs of illegal opioid use and how to prevent that use. The State claims that Pharmacies have received training from the DEA, "state pharmacy boards," and "national industry associations." Compl. ¶ 170.

⁵⁵ Compl. ¶ 186.

contends that this breach caused injury to the State of Delaware and its citizens.

Prescription Monitoring Program

Delaware has promulgated comprehensive regulation of dispensing controlled substances.⁵⁶ Section 4735(b) of Title 16 sets forth an express purpose to prevent diversion in Delaware's PMP:

(b) The Secretary, after due notice and hearing may limit, suspend, fine or revoke the registration of any registrant who:

(1) Has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels....⁵⁷

Regulation of prescription drug distribution also is contained in Delaware's Uniform Controlled Substances Act (16 *Del. C.* §§ 4701, *et seq.*), Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0 *et seq.*), code sections regarding branding of drugs (*e.g.*, 16 *Del. C.* §§ 3302, *et seq.*), and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances. These provisions provide strict controls and requirements throughout the opioid distribution chain. Delaware law also incorporates and references Federal law regarding the marketing, distribution, and

⁵⁶ 16 *Del. C.* §§ 4701 *et seq.*

⁵⁷ 16 *Del. C.* § 4735(b)(1).

sale of prescription opioids, including the Federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C §§ 321 *et seq.*

Delaware's Uniform Controlled Substances act is administered by the Secretary of State:

The Secretary shall administer this chapter. Except as otherwise provided in this chapter, the Secretary may delete or reschedule substances enumerated in the schedules of controlled substances only if:

- (1) Such substances have been deleted from or rescheduled within the federal schedules of controlled substances by the Attorney General of the United States pursuant to 21 USC § 811, *et seq.*; and
- (2) The findings required by this chapter for placement of substances in the schedules of controlled substances have been made.⁵⁸

Pharmacies' Response

Pharmacies argue that the PMP administration by Delaware's Secretary of State has exclusive jurisdiction over the regulation of prescription sales. Thus, no negligence claims may be brought by the State. However, Pharmacies concede: that the State has authority to prosecute criminal conduct; that the PMP does not prohibit medical negligence claims; and that common law negligence claims are possible. If negligence results in injury to a patient receiving a prescription, all

⁵⁸ 16 Del. C. § 4711.

“red flags” are coextensive with statutory and regulatory reporting obligations.

Pharmacies proffer *Doe v. Bradley*⁵⁹ in support of their argument that statutory duties to report misconduct do not give rise to common law negligence claims. In *Doe v. Bradley*, the Court considered “the scope of a physician's duty to report to appropriate authorities that another physician might be engaged in conduct that could endanger the health, welfare or safety of that physician's patients or the public at large.”⁶⁰ The Court found that the “[p]laintiffs’ complaint did not allege facts that would allow the court to impose a common law duty upon the medical society defendants to prevent Dr. Bradley from causing harm to the [p]laintiffs.”⁶¹ Pharmacies argue that under *Doe v. Bradley*, the regulatory scheme and enforcement procedures under Delaware law prohibit a private cause of action.

The State Has Not Stated a Claim Against Pharmacies

Delaware law requires that a medical negligence claim be accompanied by an Affidavit of Merit:

(a) No health-care negligence lawsuit shall be filed in this State unless the complaint is accompanied by:

(1) An affidavit of merit as to each defendant signed by an expert witness, as defined in § 6854 of this title, and accompanied by a current curriculum vitae of the

⁵⁹ 2011 WL 290829 (Del. Super.).

⁶⁰ 2011 WL 290829, at *1.

⁶¹ *Id.* at *4.

witness, stating that there are reasonable grounds to believe that there has been health-care medical negligence committed by each defendant....⁶²

To the extent that the State's claims fall within the definition of medical negligence, the Complaint against Pharmacies must be dismissed without prejudice to provide the State an opportunity to obtain an Affidavit of Merit.

The Court finds that the remaining allegations against Pharmacies – breaches of duties to prevent diversion – are entirely speculative and conclusory. Additionally, Delaware's comprehensive pharmacy regulatory scheme and enforcement procedures, as well as federal regulations, preempt the claims alleged in the Complaint. Therefore, Pharmacies' Motion to Dismiss must be granted. The dismissal is without prejudice as to claims sounding in medical negligence, to allow the State an opportunity to submit an Affidavit of Merit.

NUISANCE

Under Delaware law, a public nuisance is "activity which produces some tangible injury to neighboring property or persons coming into contact with it and which a court considers to be objectionable under the circumstances."⁶³

Distributors argue that the State's public nuisance claim is not cognizable

⁶² 16 Del. C. § 6853(a).

⁶³ *Patton v. Simone*, 1992 WL 398478, at *9 (Del. Super.)(citing *State v. Hill*, 167 A.2d 738, 741 (Del. Ch. 1961)).

under Delaware law. Distributors assert that Delaware Courts do not recognize products-based public nuisance claims, only property-based nuisance claims. Distributors rely on *Sills v. Smith & Wesson Corporation*⁶⁴ to support this position.⁶⁵ Distributors argue that the State has not identified or alleged a public right with which Distributors have interfered, claiming this as an essential element to a nuisance claim.

In *Sills v. Smith & Wesson Corporation*,⁶⁶ the Mayor of Wilmington sued twelve handgun manufacturers and three trade associations to recover money damages incurred by the City in connection with the design, marketing, and advertising of handguns. One of the nine counts alleged was a nuisance claim. The complaint alleged that “governmental entities may recover direct costs associated with protecting their citizens in the ‘abatement of a public nuisance.’”⁶⁷ The Court stated that “Delaware has yet to recognize a cause of action for public nuisance based upon products. Delaware public nuisance claims have been limited to situations involving land use. While no express authority exists requiring public

⁶⁴ 2000 WL 33113806 (Del. Super.).

⁶⁵ *Sills v. Smith & Wesson Corp.*, 2000 WL 33113806 (Del. Super.)(holding that Delaware law does not recognize products-based nuisance claims).

⁶⁶ 2000 WL 33113806 (Del. Super.).

⁶⁷ *Id.* at *2 (citing *City of Evansville v. Kentucky Liquid Recycling, Inc.*, 604 F.2d 1008, 1017 (7th Cir. 1979), *cert. denied*, 444 U.S. 1025 (1980)(costs of abating toxic waste public nuisance are recoverable); *U.S. v. Occidental Chem. Corp.*, 965 F.Supp. 408, 412–413 (W.D.N.Y. 1997) (exercise of police power to protect public health in abating toxic waste public nuisance are recoverable)).

nuisance claims be restricted to those based on land use, Delaware courts remain hesitant to expand public nuisance.”⁶⁸ The Court held that there was “no independent claim for public nuisance” and refused to recognize a public nuisance claim for products.⁶⁹

Other jurisdictions also have refused to allow products-based public nuisance claims. There is a clear national trend to limit public nuisance to land use.⁷⁰

On December 28, 2018, the State submitted to the Court supplemental authority related to briefing on Defendants’ Motions to Dismiss, attaching an opinion issued by MDL Judge Dan Aaron Polster of the United States District Court for the Northern District of Ohio. This Court concurs with Judge Polster as

⁶⁸ *Id.* at *7.

⁶⁹ *Id.*

⁷⁰ See, e.g., *Tioga Public School Dist. No. 15 of Williams County, State of N.D. v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993) (“to interpret the nuisance statute in the manner espoused by Tioga would in effect totally rewrite North Dakota tort law”); *State v. Lead Industries, Ass’n, Inc.*, 951 A.2d 428, 456 (R.I. 2008) (“[t]he law of public nuisance never before has been applied to products, however harmful”); *In re Lead Paint Litig.*, 924 A.2d 484, 505 (N.J. 2007) (“were we to permit these complaints to proceed, we would stretch the concept of public nuisance far beyond recognition and would create a new and entirely unbounded tort antithetical to the meaning and inherent theoretical limitations to the tort of public nuisance”); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004) (“there is no authority for the unprecedented expansion of the concept of public rights to encompass the right asserted by plaintiffs...the plaintiff’s claim does not meet all of the required elements of a public nuisance action”); *People ex re. Spitzer v. Sturm, Ruger & Co., Inc.*, 761 N.Y.S. 2d 192, 196 (N.Y. App. Div. 2003) (“giving a green light to a common-law public nuisance cause of action today will, in our judgment, likely open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities”).

to the vast majority of his conclusions. However, the Court finds this supplemental authority distinguishable from the State's case regarding the public nuisance claim.

Judge Polster's Opinion discusses in great detail Ohio legislative history relating to product liability and nuisance claims. The Opinion determined that "in light of the legislative history, the Court finds it at least plausible, if not likely, that the 2005 and 2007 Amendments to the OPLA intended to clarify the definition of 'product liability claim' to mean 'a claim or cause of action [including any common law negligence or public nuisance theory of product liability...] that is asserted in a civil action...that seeks to recover compensatory damages...for [harm]....'"⁷¹

There is no comparable legislative history in Delaware.

The State only has alleged a public nuisance claim. The State has not alleged a product liability claim, nor has it asked the Court to determine whether Delaware product liability law contemplates a public nuisance claim. In Delaware, public nuisance claims have not been recognized for products.⁷²

The State has failed to allege a public right with which Defendants have interfered. A defendant is not liable for public nuisance unless it exercises control

⁷¹ *In re National Prescription Opiate Litigation*, No. 1:17-md-2804 (6th Cir. 2018), <http://courtweb.pamd.uscourts.gov/courtwebsearch/ndoh/BOTExQ3LV4.pdf>.

⁷² *Sills v. Smith & Wesson Corp.*, 2000 WL 33113806, at *7 (Del. Super.).

over the instrumentality that caused the nuisance at the time of the nuisance.⁷³ The State has failed to allege control by Defendants over the instrumentality of the nuisance at the time of the nuisance. Thus, all Defendants' Motions to Dismiss the nuisance claims must be granted.

CIVIL CONSPIRACY

To establish a valid claim for civil conspiracy, a plaintiff must prove: “(1) A confederation or combination of two or more persons; (2) An unlawful act done in furtherance of the conspiracy; and (3) Actual damage.”⁷⁴ “In Delaware, ‘civil conspiracy is not an independent cause of action...it must arise from some underlying wrong.’”⁷⁵

The State argues that Manufacturers “have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids.”⁷⁶ The State argues that “[w]ithout Manufacturer Defendants’ misrepresentations, which created demand, Distributor Defendants would not have been able to sell to Pharmacy Defendants the increasing number of

⁷³ *Patton v. Simone*, 1992 WL 183064, at *13 (Del. Super.).

⁷⁴ *Johnson v. Preferred Professional Ins. Co.*, 91 A.3d 994, 1014 (Del. Super.)(citing *Nicolet, Inc. v. Nutt*, 525 A.2d 146, 149–50 (Del. 1987)(citing *McLaughlin v. Copeland*, 455 F.Supp. 749, 752 (D.Del. 1978), *aff’d*, 595 F.2d 1213 (3d Cir. 1979))).

⁷⁵ *Id.* at 1014 (citing *Ramunno v. Cawley*, 705 A.2d 1029, 1030 (Del. 1998)).

⁷⁶ Compl. ¶ 303.

orders of prescription opioids for non-medical purposes throughout Delaware.”⁷⁷

The State asserts that “[w]ithout Distributor Defendants’ supply of prescription opioids, Pharmacy Defendants would not have been able to fill and dispense the increasing number of orders of prescription opioids for non-medical purposes throughout Delaware.”⁷⁸ The State alleges that this chain of conduct lead to damages suffered by the State of Delaware and its citizens.

“There is no such thing as a conspiracy to commit negligence or, more precisely, to fail to exercise due care.”⁷⁹ However, in *Nicolet, Inc. v. Nutt*,⁸⁰ the Delaware Supreme Court found allegations of intentional misrepresentation of fraudulent concealment sufficient to support the plaintiffs’ claim that a manufacturer participated in an industry-wide conspiracy to conceal the health hazards of asbestos.⁸¹

In order to allege a *prima facie* case of fraudulent concealment, a plaintiff must show: “(1) deliberate concealment of a material fact or silence in the face of a duty to speak; (2) scienter; (3) intent to induce reliance upon the concealment; (4) causation; and (5) resulting damage.”⁸² In *Nicolet*, the Delaware Supreme Court

⁷⁷ Compl. ¶ 305.

⁷⁸ Compl. ¶ 306.

⁷⁹ *Szczerba v. American Cigarette Outlet, Inc.*, 2016 WL 1424561, at *3 (Del. Super.)(citing *Anderson v. Airco, Inc.*, 2004 WL 2827887 (Del. Super.)(citing *Ryan v. Eli Lilly & Co.*, 514 F.Supp. 1004, 1012 (D.S.C.1981))).

⁸⁰ 525 A.2d 146 (Del. 1987).

⁸¹ *Id.* at 149.

⁸² *Szczerba*, 2016 WL 1424561, at *3 (citing *Nicolet*, 525 A.2d at 149-50).

found that the plaintiffs met these elements, reasoning:

[P]laintiffs claim ... the conspiracy, which allegedly included [defendant], caused “to be positively asserted to plaintiffs in a manner not warranted by the information possessed by said defendants, ... that it was safe ... to work in close proximity to [the] [asbestos] materials” and ... suppressed “medical and scientific data and other knowledge, causing plaintiffs to be and remain ignorant thereof.” The complaint clearly alleges scienter in that the participants “knowingly and willfully conspired” in the scheme ... [and] alleges an intent ... to induce ... reliance on false or incomplete material facts. In our opinion these allegations are sufficient to state a tort claim based on a theory of fraudulent concealment.⁸³

In this case, the Court finds that the State has not adequately alleged in its Complaint that Defendants engaged in a civil conspiracy similar to the allegations in *Nicolet*. The State has merely alleged parallel conduct by Defendants, making no claims that “the participants ‘knowingly and willfully conspired’ in the scheme”⁸⁴ in order to induce reliance. The State has not alleged that the Defendants intended to conspire, but merely stated at oral argument that Defendants attended the same conferences. There are no allegations of a concerted action, an agreement to commit an underlying wrong, awareness of an agreement, or action in accordance with that agreement. The State argues that “Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants need not have expressly agreed to this course of action; concerted conduct itself is sufficient.”

⁸³ *Nicolet*, 525 A.2d at 149.

⁸⁴ *Id.*

This argument is not supported by Delaware law.

The Civil Conspiracy claims are hereby dismissed without prejudice. The claims may be added if evidence supporting a conspiracy surfaces during discovery.

UNJUST ENRICHMENT

Delaware law defines unjust enrichment as “the unjust retention of a benefit to the loss of another, or the retention of money or property of another against the fundamental principles of justice or equity and good conscience.”⁸⁵ Unjust enrichment requires the following: (1) an enrichment; (2) an impoverishment; (3) a relation between the enrichment and the impoverishment; (4) the absence of justification; and (5) the absence of a remedy provided by law.⁸⁶

Under Delaware law, unjust enrichment is not a stand-alone claim in Superior Court. The claim must be brought in the Court of Chancery. In this Court, unjust enrichment may be asserted as a possible measure of damages. Therefore, the unjust enrichment claim must be dismissed.

⁸⁵ *Incyte Corporation v. Flexus Biosciences, Inc.*, 2017 WL 7803923, at *4 (Del. Super.)(citing *Nemec v. Shrader*, 991 A.2d 1120, 1130 (Del. 2010)).

⁸⁶ *See Nemec v. Shrader*, 991 A.2d 110, 1130 (Del. 2010).

ENDO PHARMACEUTICALS INC.'S MOTION TO STRIKE

Endo argues that to the extent that the State relies on references to a 2016 Assurance of Discontinuance (AOD) between the New York Attorney General and Endo, those allegations should be stricken or, at a minimum, cannot form the basis of the State's claims. Endo also argues that the AOD was made without Endo admitting to any of the findings of the New York Attorney General's investigation. The parties allegedly agreed that the AOD was not intended for use by any third party in any other proceeding and is not intended, and should not be construed, as an admission by Endo of any liability or finding set forth hererin."⁸⁷ Endo argues that the State is trying to use the settlement against Endo. Endo claims that many courts have stricken as immaterial and impertinent allegations that refer to or are derived from settlements and other preliminary or non-adjudicated proceedings, including governmental investigations.

The State claims that it is only using two findings from the New York Attorney General's investigation, which Endo did not admit. Further, the settlement is not an admission by Endo, but the statements quoted by the State in its Complaint are the New York Attorney General's findings, and the State has a right to use them. The State contends that it is not using the findings to establish

⁸⁷ Assurance of Discontinuance ¶¶ 54, 67 (Endo requested in its Motion to Dismiss that the Court take judicial notice of the AOD, an executed copy of which is available on the NYAG's website.); See https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

Endo's liability, but to help refute Endo's contention that the State has not stated a claim. The State argues that pleadings are not evidence of liability and are more properly a subject of a motion *in limine*.⁸⁸

When ruling on a motion to strike, the Court considers: (1) whether the challenged averments are relevant to an issue in the case; and (2) whether they are unduly prejudicial.⁸⁹ "Motions to strike are not favored and are granted sparingly, and then only if clearly warranted, with doubt being resolved in favor of the pleading, and objectionable matter will be stricken only if it is clearly shown to be unduly prejudicial."⁹⁰

The Court finds that the matters objected to in Endo's motion are relevant and have not been shown to be unduly prejudicial. Therefore, Endo's Motion to Strike Paragraph 83 of the Complaint must be denied.

⁸⁸ The State proffers *Johnson v. M&M*, 242 F.R.D. 187, 190 (D. Conn. 2007) ("a complaint is not submitted to the jury" and "whether evidence of the prior investigations will be admissible at trial is an issue to be resolved at a later stage").

⁸⁹ See *Shaffer v. Davis*, 1990 WL 81892, at *4 (Del. Super.) (citing *Pack & Process, Inc. v. Celotex Corp.*, 503 A.2d 646, 660-61 (Del. Super. 1990)).

⁹⁰ *Pack & Process, Inc. v. Celotex Corp.*, 503 A.2d 646, 660-61 (Del. Super. 1985).

CONCLUSION

The Court finds that the State of Delaware has established a *prima facie* case for Negligence and Consumer Fraud against the Manufacturer Defendants, Anda Pharmaceuticals, and the Distributor Defendants. However, the State of Delaware has not demonstrated a *prima facie* case for Negligence and Consumer Fraud claims against the Pharmacy Defendants. **Therefore, Manufacturer Defendants', Distributor Defendants', and Anda Pharmaceuticals' Motions to Dismiss the Negligence and Consumer Fraud claims are hereby DENIED. Pharmacy Defendants' Motion to Dismiss the Negligence and Consumer Fraud claims is hereby GRANTED.**

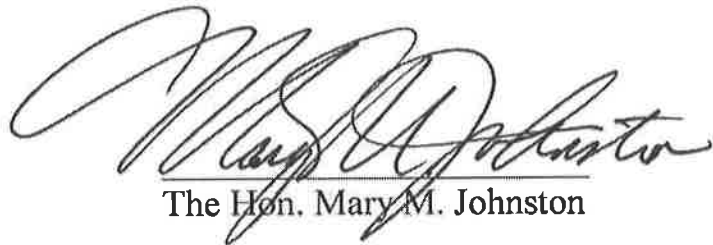
The Court finds that the State of Delaware's nuisance claims fail as a matter of law. **Therefore, all Motions to Dismiss the Nuisance claims are hereby GRANTED.**

The Court finds that the State of Delaware has failed to adequately plead its civil conspiracy claim because the State only asserts parallel conduct by Defendants and has failed to establish a *prima facie* case involving concerted action, agreement, awareness of the agreement, and action in accordance with that agreement. **Therefore, all Motions to Dismiss the Civil Conspiracy claims are hereby GRANTED, without prejudice. Claims for Civil Conspiracy may be added if such evidence surfaces during discovery.**

The Court finds that the State of Delaware's unjust enrichment claim is not a stand-alone claim at law. This claim must be brought in the Court of Chancery. Unjust enrichment may be asserted as a possible measure of damages. **Therefore, all Motions to Dismiss the Unjust Enrichment claims are hereby GRANTED.**

The Court finds that the matter objected to in Endo Pharmaceutical's Motion to Strike Paragraph 83 of the Complaint has not been shown to be unduly prejudicial. **Therefore, Endo Pharmaceutical's Motion to Strike Paragraph 83 of the Complaint is hereby DENIED.**

IT IS SO ORDERED.



The Hon. Mary M. Johnston